UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, *et al.* *ex rel.* TRICIA NOWAK & ENDA DODD,

Plaintiffs,

v.

MEDTRONIC, INC.,

Defendant.

Nos. 1:08-cv-10368 & 09-cv-11625 (DPW)

CONSOLIDATED COMPLAINT FOR VIOLATIONS OF THE FALSE CLAIMS ACT [31 U.S.C. § 3729, *et seq.*]; CALIFORNIA FALSE CLAIMS ACT [CAL. GOV'T CODE § 12650, *et seq.*]; DELAWARE FALSE CLAIMS AND FALSE REPORTING ACT [6 DEL. CODE. ANN. § 1431, *et seq.*]; FLORIDA FALSE CLAIMS ACT [FLA. STAT. ANN. § 68.081, *et seq.*]; GEORGIA STATE FALSE MEDICAID CLAIMS ACT [O.C.G.A. § 49-4-168, *et seq.*]; HAWAII FALSE CLAIMS ACT [HAW. REV. STAT. § 661-21, *et seq.*]; ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT [740 ILL. COMP. STAT. § 175/3, *et seq.*]; INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT [IND. CODE ANN. § 5-11-5.5-1, *et seq.*]; LOUISIANA MEDICAL ASSISTANCE PROGRAM INTEGRITY LAW [LA. REV. STAT. § 46:437.1, *et seq.*]; MASSACHUSETTS FALSE CLAIMS LAW [MASS. GEN. LAWS ch.12 § 5, *et seq.*]; MICHIGAN MEDICAID FALSE CLAIMS ACT [MICH. COMP. LAWS § 400.601, *et seq.*]; MONTANA FALSE CLAIMS ACT [MONT. CODE ANN. § 17-8-401, *et seq.*]; NEVADA FALSE CLAIMS ACT [NEV. REV. STAT. ANN. § 357.010, *et seq.*]; NEW HAMPSHIRE FALSE CLAIMS ACT [N.H. REV. STAT. ANN. § 167:61, *et seq.*]; NEW JERSEY FALSE CLAIMS ACT [N.J. STAT. ANN. § 2A:32C-1, *et seq.*]; NEW MEXICO MEDICAID FALSE CLAIMS ACT [N.M. STAT. ANN. § 27-14-1, *et seq.*]; NEW YORK FALSE CLAIMS ACT [N.Y. CLS ST. FIN. § 187, *et seq.*]; OKLAHOMA MEDICAID FALSE CLAIMS ACT [OKLA. STAT. 63 § 5053 *et seq.*]; RHODE ISLAND STATE FALSE CLAIMS ACT [R.I. GEN. LAWS § 9-1.1-1 *et seq.*]; TENNESSEE MEDICAID FALSE CLAIMS ACT [TENN. CODE ANN. § 71-5-181, *et seq.*]; TEXAS MEDICAID FRAUD PREVENTION LAW [TEX. HUM. RES. CODE ANN. § 36.001, *et seq.*]; VIRGINIA FRAUD AGAINST TAXPAYERS ACT [VA. CODE ANN. § 8.01-216.1, *et seq.*]; WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE ACT [WIS. STAT. § 20.931 *et seq.*]; and the DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT [D.C. CODE ANN. § 2-308.13, *et seq.*].

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Plaintiffs and Relators Tricia Nowak and Enda Dodd, through their respective attorneys, on behalf of the United States of America, the State of California, the State of Delaware, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Louisiana, the State of Massachusetts, the State of Michigan, the State of Montana, the State of Nevada, the State of New Hampshire, the State of New Jersey, the State of New Mexico, the State of New York, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the State of Virginia, the State of Wisconsin, and the District of Columbia (collectively "the States"), in this Consolidated Complaint against Defendant Medtronic, Inc., allege based upon personal knowledge and relevant documents, as follows.

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States and the States arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used or presented by Defendant Medtronic, Inc. ("Medtronic") and/or its agents and employees in violation of the False Claims Act, 31 U.S.C. § 3729, as amended, and the State statutes specified below. The action also seeks to recover damages on behalf of Ms. Nowak under the False Claims Act, 31 U.S.C. § 3730(h), the California False Claims Act § 12653(B), and California common law, said damages having resulted from Medtronic's unlawful discrimination and retaliation against, and termination of, Ms. Nowak for her protected activity taken in furtherance of stopping violations of the False Claims Act.

2. Recovery on behalf of the States is sought for damages arising from Medtronic's violations of the California False Claims Act, CAL. GOV'T CODE § 12650, *et seq.*; the Delaware False Claims and False Reporting Act, 6 DEL. CODE ANN. § 1431, *et seq.*; the Florida False Claims Act, FLA. STAT. ANN. § 68.081, *et seq.*; the Georgia State False Medicaid Claims Act, O.C.G.A. § 49-4-168, *et seq.*, the Hawaii False Claims Act, HAW. REV. STAT. § 661-21, *et seq.*;

the Illinois Whistleblower Reward and Protection Act, 740 ILL. COMP. STAT. § 175/3, *et seq.*; the Indiana False Claims and Whistleblower Protection Act, IND. CODE ANN. § 5-11-5.5-1, *et seq.*; the Louisiana Medical Assistance Program Integrity Law, LA. REV. STAT. § 46:437.1, *et seq.*; the Massachusetts False Claims Law, MASS. GEN. LAWS CH. 12 § 5, *et seq.*; the Michigan Medicaid False Claims Act, MICH. COMP. LAWS. § 400.601, *et seq.*; the Montana False Claims Act, MONT. CODE ANN. § 17-8-401, *et seq.*; the Nevada False Claims Act, NEV. REV. STAT. ANN. § 357.010, *et seq.*; the New Hampshire False Claims Act, N.H. REV. STAT. ANN. § 167:61, *et seq.*; the New Jersey False Claims Act, N.J. STAT. ANN. § 2A:32C-1, *et seq.*; the New Mexico Medicaid False Claims Act, N.M. STAT. ANN. § 27-2F-1, *et seq.*; the New York False Claims Act, N.Y. CLS ST. FIN. § 187, *et seq.*, the Oklahoma Medicaid False Claims Act, OKLA. STAT. 63 § 5030, *et seq.*, the Rhode Island State False Claims Act, R.I. GEN. LAWS § 9-1.1-1 *et seq.*, the Tennessee Medicaid False Claims Act, TENN. CODE ANN. § 71-5-181, *et seq.*; the Texas Medicaid Fraud Prevention Law, TEX. HUM. RES. CODE ANN. § 36.001, *et seq.*; the Virginia Fraud Against Taxpayers Act, VA. CODE ANN. § 8.01-216.1, *et seq.*; the Wisconsin False Claims for Medical Assistance Act, WIS. STAT. § 20.931 *et seq.*, and the District of Columbia Procurement Reform Amendment Act, D.C. CODE ANN. § 2-308.13, *et seq.*

3. For several years, Medtronic, the world's largest medical technology company with nearly 38,000 employees, has unlawfully and unabashedly developed, marketed and promoted its biliary stent medical devices for uses unapproved by the Food and Drug Administration ("FDA"). Medtronic, a Fortune 200 company with nearly $15 billion in revenue for fiscal year 2009, has knowingly promoted the unapproved, or "off-label," application of these medical devices in contravention of federal law and explicit, repeat warnings from the FDA. As discussed below, Medtronic has successfully orchestrated its fraud on the FDA by submission of

false statements in support of marketing clearance for peripheral (*i.e.,* outside the heart) vascular devices masquerading as non-vascular biliary devices. By doing this, Medtronic violates the law and put patients at serious risk.

4. Medtronic falsely certifies to FDA, in each of its biliary device approval applications, that its devices have been designed as and intended solely for use as biliary stents. In fact, Medtronic never intended, by design or promotion, that these devices be used as biliary stents – they have been designed and promoted off-label as vascular stents.

5. As explained in what follows, Medtronic has pressured and incentivized its vast sales force to promote biliary stent devices for peripheral vascular uses for which they are unapproved, and ineligible for reimbursement under various government health care programs, including Medicare.

6. While unlawfully creating demand in the medical community for off-label application of its biliary stents, Medtronic circumvents FDA's regulatory safeguards for the use of approved medical devices. It does this, and has done so historically, by submitting false certifications and statements to get FDA approval of its biliary devices where it does not design the device nor intend to promote the proposed use of the device as claimed in those submissions. Such circumvention relieves Medtronic of the expense and time needed to satisfy the requirements for FDA approval of such devices for additional uses.

7. The off-label promotional efforts of Medtronic have resulted in at least 90% of the uses for its biliary stents now being off-label, and an off-label market for biliary stents in the hundreds of millions of dollars. This off-label market has increased Medtronic's profits at the expense of public safety, patient health and the public fisc. This unlawful practice also gives Medtronic an unfair competitive advantage over those companies who have spent, and continue

to spend, time and money to secure FDA approval for their *on-label* medical devices in the same market.

8. As a direct result of Medtronic's unlawful marketing campaign, federal and state health care programs including, but not limited to, Medicare, Medicaid, Medi-Cal, CHAMPUS/TRICARE, CHAMPVA, the Veterans Administration and the Federal Employee Health Benefits Program have been caused to pay false or fraudulent claims for reimbursement of costs associated with the off-label use of biliary stents among patients for whom biliary stents are unapproved for use in the medical procedures they undergo. Such Government payors have also been deceived into paying reimbursement for use of devices not properly marketed nor lawfully placed into service due to the false certifications and statements made by Medtronic to get FDA approval for these devices. These devices are both misbranded and adulterated, as those terms are defined under federal law regulating medical devices.

9. *Qui tam* Plaintiffs seek through this action to recover damages and civil penalties arising from Medtronic's making or causing to be made false or fraudulent records, statements and/or claims in connection with its applications for FDA approval of biliary stents and the marketing of its biliary stents for off-label purposes. Medtronic has knowingly caused the submission of innumerable claims to federal and state health insurance programs for non-FDA-approved and potentially harmful off-label uses of biliary stents, stents which are in fact "adulterated" devices. 21 U.S.C. § 351(f). The law does not provide for government payment of such off-label use, and only through its fraud has Medtronic caused such government payments to be made.

10. Medtronic retaliated against and ultimately terminated the employment of both Relators because of their protected activity objecting to the off-label design, manufacture, and

promotion of its biliary stents. Ms. Nowak additionally seeks in this action to recover damages resulting from Medtronic's discrimination in retaliating against her.

II. PARTIES

11. Plaintiff/Relator Ms. Tricia Nowak is a resident of the State of California. From May of 2005 until her retaliatory termination on August 7, 2009, Ms. Nowak was employed by Medtronic as a Sales Representative in its Endovascular Group. In that capacity she, like all Vascular Division sales reps, was instructed to promote and sell biliary stents for off-label vascular use.

12. Plaintiff/Relator Mr. Enda Dodd is a resident of the State of California. He began work in Ireland as a Senior Engineer for C.R. Bard in 1987, which was subsequently acquired by AVE (Advanced Vascular Engineering, Inc.). AVE was itself acquired later by Medtronic in 1999. In 2003, Mr. Dodd moved to Santa Rosa, California to become a Senior Research Manager with Medtronic. In that capacity Mr. Dodd oversaw the research and development of peripheral vascular products for Medtronic, including biliary stents designed and promoted for off-label vascular use.

13. Defendant Medtronic, Inc., is a publicly traded company listed on the NYSE, with corporate headquarters and its principal place of business in Minneapolis, Minnesota. Medtronic is a medical device manufacturer that markets, promotes, and sells its devices in this District, across the United States, and around the world. Medtronic designs, promotes and sells its biliary stent medical devices for off-label vascular use.

III. JURISDICTION AND VENUE

14. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions, such as this, brought pursuant to 31 U.S.C. § 3730(b) for violations of § 3729.

In addition, 31 U.S.C. § 3732(b) specifically confers jurisdiction on this Court over the state-law claims made here, and supplemental jurisdiction is provided by 28 U.S.C. § 1367(a). Under 31 U.S.C. § 3730(e), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint.

15. This Court has personal jurisdiction over the Defendant and is a proper venue pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a). The Defendant can be found in, resides, transacts, or has transacted business in the District of Massachusetts.

16. At all times relevant to this Complaint, Defendant regularly conducted substantial business, including off-label promotion of biliary devices, within the District of Massachusetts, and made significant sales within the District of Massachusetts.

IV. BACKGROUND

A. FDA Regulation of Medical Devices

17. In 1976, Congress enacted the Medical Device Amendments ("MDA"), 21 U.S.C. § 360*c, et seq.*, to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.,* in order to synchronize FDA regulation of medical devices with that of pharmaceutical products, and "to provide for the safety and effectiveness of medical devices intended for human use." Pub. L. No. 94-295, 90 Stat. 539, 539 (1976) (preamble). The MDA expanded the authority of the FDA to regulate medical devices, a business that has since grown exponentially into a multi-billion dollar industry, consisting of over 100,000 products in nearly 2,000 medical categories. The Center for Devices and Radiological Health ("CDRH") operates within the FDA to regulate medical devices.

18. A "medical device" is broadly defined as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is – (1) recognized by the official National Formulary, or

the United States Pharmacopeia (USP), or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in a man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of the man or other animals, and which is not dependent upon being metabolized for the achievement of its principal intended uses." 21 U.S.C. § 321(h).

19. Under the MDA, medical devices are divided into three categories, or "classes." Class I devices (such as bandages and sterile gloves) are subject to minimal regulation; Class II devices (such as powered wheelchairs and surgical drapes) are subject to moderate regulation; and Class III devices, those devices that either "present a potential unreasonable risk of illness or injury," or which are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," are subject to the strictest controls. 21 U.S.C. § 360*c*(a)(1)(C). Biliary stents are approved by FDA as Class II devices; vascular stents are approved as Class III devices.

20. Class III devices are the riskiest devices. Such devices may not be introduced into the market until and unless the FDA has approved the device for its "intended use," that is, the use intended by the manufacturer, or, "the objective intent of the persons legally responsible for the labeling of the devices." 21 C.F.R. § 801.4. Three routes exist for manufacturers of Class III devices to obtain FDA approval. Most commonly, manufacturers seek "premarket approval" ("PMA") from the FDA, establishing, through extensive and lengthy review of data from clinical trials, bench and animal tests, "reasonable assurance" that the device is safe and effective for its intended use. 21 U.S.C. § 360*e*(d)(2).

21. To obtain PMA for a given device, FDA demands a complete report of all clinical and laboratory testing, a full statement of the components and design of the product, a description of the manufacturing process and quality controls, sample labeling instructions, and other detailed information. 21 U.S.C. § 360*e*(c)(1). This rigorous process requires the FDA to spend an average of 1430 hours reviewing and evaluating each such application, often in lengthy discussions with the manufacturer regarding safety and other concerns. For manufacturers like Medtronic, the process is necessarily prolonged, rigorous, and costly, ensuring (one hopes) that FDA releases for commercialization only those devices (and indicated uses) that can safely be utilized among high-risk patients hoping to save their lives.

22. Two limited and exclusive exceptions to the PMA process exist for manufacturers seeking to introduce their medical devices to consumers. First, a device can be sold if cleared by the FDA under the so-called 510(k) process, whereby the manufacturer can market and sell a device which is a "substantial equivalent" to a device already approved for the same use, where it certifies that the information submitted pursuant to the 510(k) process is "truthful and accurate." 21 U.S.C. § 360; 21 C.F.R. § 807.87(k). The manufacturer must obtain a clearance letter from FDA permitting it to market the device in question for indicated uses. The 510(k) process is far less demanding for manufacturers like Medtronic, and typically requires only simple, straightforward testing rather than exhaustive clinical testing. It is well understood that "substantial equivalence" to an already approved device is not a high threshold to reach.

23. Still, Medtronic and other manufacturers must certify in their 510(k) application the intended use of the device, a description of the conditions the device is designed and intended to treat, and the patient population it targets. 21 C.F.R. § 807.92(a)(5). Each submission must explicitly include a statement by an agent on behalf of the manufacturer that he or she "believes,

to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted." 21 C.F.R. § 807.87(k). Medtronic has falsely certified compliance with this requirement in each of its applications for approval of its line of biliary stents.

24. Second, devices judged to reflect innovative technology may be marketed under a restricted "investigational device exemption," or "IDE," for purposes of conducting investigations of that device. 21 U.S.C. § 360*j*(g); 21 C.F.R. § 812.1. None of Medtronic's biliary stents have been approved by the FDA under the IDE exception.

25. A medical device may not lawfully be marketed or promoted for a use not previously approved by the FDA under at least one of the three routes described above – the PMA process, the 510(k) process, or the IDE process. Relevant here, a manufacturer may not promote a medical device approved via the 510(k) process for any use not explicitly disclosed by the company and approved by FDA as part of its application process.

26. A medical device is only approved on the basis of its intended use, or approved "indication," which must then be included in the device's labeling. 21 U.S.C. § 352(f); 21 C.F.R. § 801.5. A medical device is not approved *in general*. If the manufacturer wishes to market a new, unapproved use for a device, it must first obtain FDA approval (through one of the routes explained above) so that its labeling is changed to indicate the limits of any FDA approval of such additional or substitute uses. 21 C.F.R. § 807.81(a)(3). A manufacturer may not promote a device off-label as a means of circumventing FDA's approval process designed to safeguard public health.

27. A medical device is deemed "misbranded," and its sale and promotion therefore unlawful, where, *inter alia*, it is promoted or otherwise marketed in a manner inconsistent with

its approved FDA label. 21 U.S.C. § 331, 352. "Off-label" refers to the promotion or use of an approved medical device for any purpose, or in any manner, other than what is stated in the product's labeling (*i.e.*, what has been approved by the FDA as an "indication"). Off-label promotion, that is, promotion by the manufacturer of a medical device for an unapproved use, is unlawful, and renders a medical device "misbranded." This is because, in that instance, the manufacturer's actual "intended use," *i.e.*, the use for which they are promoting the medical device, is inconsistent with the "intended use" approved by the FDA, and therefore the promotion is off-label.

28. What the manufacturer "intends" is determined by the "expressions" of the manufacturer (or its agents) in promoting the device, or "by the circumstances surrounding [its] distribution." 21 C.F.R. § 801.4. "This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by [the manufacturer] or their representatives. It may be shown by the circumstances that the [device] is, with the knowledge of [*inter alia*, manufacturers] or their representatives, offered and used for a purpose for which it is neither labeled nor advertised." *Id.* Importantly, "if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device that accords with such other uses to which the article is put to be." *Id.*

29. Once a device is approved for a particular use, the FDA does not prohibit doctors from *using* that device for purposes different than those approved by the FDA – the manufacturer, however, is prohibited from *promoting* any unapproved use.

30. The prohibition on off-label promotion by medical device manufacturers protects patients and consumers by seeking to ensure that manufacturers do not promote their devices for uses other than those found to be safe and effective by an independent, scientific governmental body – the FDA.

B. FDA Regulation of Biliary and Vascular Stents

31. A medical stent refers to a tubular-shaped device inserted into tubular-like structures in the body. Stents are variously used in blood vessels (vascular) and bile ducts (biliary) among other areas of the body. Broadly speaking, a patient receives a stent implant to prevent or treat an obstruction in a pathway of the body, helping to sustain proper flow of, for example, blood in vessels. Each model of stent, and each class of stents, is functionally and compositionally different from others based upon its intended use. Like all medical devices, the FDA regulates both biliary and vascular stents. The FDA, and federal law, also recognizes the critical difference between the two; biliary stents are Class II devices, vascular stents are high-risk Class III devices. It is abundantly clear that these devices are not interchangeable.

32. Federal law classifies all biliary stents as Class II medical devices. 21 C.F.R. § 876.5010(b). They are defined as "tubular flexible device[s] used for temporary or prolonged drainage of the biliary tract, for splinting of the bile duct during healing, and for preventing strictures of the bile duct. This generic type of device may include a bile collecting bag that is attached to the biliary catheter by a connector and fastened to the patient with a strap." *Id.* at § 876.5010(a).

33. Biliary stents are typically implanted in patients suffering from late-stage cancer. They are inserted by gastroenterologists and interventional radiologists as merely palliative measures to address malignant strictures in the pancreas, stomach, or liver. Since they are not intended for life-long use, or to save lives, and are not inserted into the vasculature or other such

systems, only moderate risk is associated with their use. For these reasons, rigorous long-term clinical studies of biliary stents are not required, and Class II designation suffices to protect public safety where the devices are used on-label. The CDRH's Division of Reproductive, Abdominal and Radiological Devices reviews for approval a variety of Class I and II medical devices including biliary stents, condoms, fetal monitors, tampons, and other non-vascular medical devices.

34. Vascular stents are altogether different. Peripheral vascular stents are regulated as Class III medical devices because they are high-risk. They are intended to treat and hopefully cure peripheral vascular disease by relieving and preventing obstruction of the blood vessels. Vascular stents are categorized by the particular vascular area they are designed to treat, *e.g.*, iliac artery, renal artery, or superficial femoral artery. As Daniel Schultz, M.D., then-Director of CDRH, noted in testimony before the Senate in September 2008 – "In contrast [to biliary stents], vascular stents have been reviewed and approved as Class III devices, following submission of PMA applications containing additional pre-clinical testing and clinical study data." Vascular stents are subject to far more rigorous scrutiny before they are approved because unlike biliary stents, they are not palliative. As the FDA has explained, "[s]tents to be used in the vasculature undergo more extensive bench testing than biliary stents because they are expected to remain implanted longer and are subjected to significantly different environments and forces *in vivo*, including a range of pulsatility, flow rates, pressures, and contractile forces depending on the location of deployment."[1] Vascular stents are, simply put, intended to save lives for patients at great risk of peripheral-vascular-related death and are intended to be permanent device implants.

[1] Yustein, Aron, M.D., Schultz, Daniel, M.D., *et al.*, "U.S. Food and Drug Administration and Off-Label Use of Expandable Metal Biliary Stents Within the Peripheral Vasculature," J. Vasc.

35. According to the American Cancer Society, in 2007 the U.S. incidence of pancreatic cancer and bile duct cancer were approximately 37,170 and 4,600 persons respectively. Biliary stents are ostensibly available to treat some segment of those afflicted with such diseases. By contrast, peripheral vascular disease afflicts millions of Americans, and the market for vascular stent use is exponentially greater. As the CDRH noted in its 2008 Special Communication, "[d]espite the limited population afflicted with malignant biliary obstruction, more than 50 biliary stent model lines, each in various combinations of length and diameter, have been marketed in the United States by more than a dozen manufacturers," including Medtronic.[2] The obvious reason for such volume and variety of biliary stents is that these devices are intended by the manufacturers for vascular use, to treat the vastly larger vascular disease population.

36. In order to obtain FDA approval for a vascular stent, stent manufacturers must spend significant time and resources. "Clinical data [from clinical trials] are requested for all original vascular stent applications," according to FDA.[3] Further, such "trials are considered 'high-risk' and, when conducted in the United States, require an FDA-approved Investigational Device Exception [IDE] in addition to institutional board review."[4] Because of the expense involved, "far fewer PMA applications have been submitted and approved for metal peripheral vascular stents when compared to 510(k) submissions for biliary stents."[5]

37. According to FDA's Office of Device Evaluation FY 06-07 Annual Report, "over the past several years, FDA has become increasingly concerned about off-label promotion and

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Interv. Radiol., 19:965-969 at 967 (2008) (Special Communications from the CDRH, all authors are employees of the FDA) (hereafter "Special Communication").
[2] *Id.*, Special Communication at 966.
[3] *Id.* at 967.
[4] *Id.*
[5] *Id.*

use of expandable metal biliary stents within the peripheral vascular system." In fact, "[b]ecause of FDA's concerns regarding off-label use, since 1999 manufacturers marketing expandable biliary stents have been required to prominently display the biliary indication in all labeling and to include a warning stating that the device's safety and effectiveness in the vascular system have not been established."

38. Out of this growing concern that manufacturers, including Medtronic, were improperly seeking approval for Class II biliary stents with intent to promote them as Class III vascular stents, and following earlier unheeded FDA warnings, the FDA in March of 2007 summoned Medtronic and others to "discuss off-label promotion and use of biliary stents in vascular applications," reminding them of their obligations under the law. This concern arose because none of Medtronic's biliary stents are intended for biliary use, though none were submitted for their actual vascular use, nor ever tested or evaluated by FDA to ensure their public safety for such off-label use.[6] More importantly, as detailed in its aforementioned Annual Report, "FDA has noticed an increase in the number of Medical Device Reports being submitted for biliary stents used off-label," with reports including "deaths resulting from vessel structural damage and cardiac arrhythmias and infarctions." Unfortunately for patients, and taxpayers, efforts by the FDA have failed to prevent Medtronic from continuing its off-label manufacture and promotion of biliary stents for vascular use.

[6] Medtronic briefly gained PMA approval for its BRIDGE stent system in May of 2003 to treat renal conditions, but this device was quickly replaced by the RACER stent, approved only for biliary use. Any promotion or sale of the renal-indicated BRIDGE was short-lived, and replaced quickly by off-label promotion of the new RACER stent.

C. Reimbursement of Medical Devices Under Federal Health Care Programs

1. The Medicare program

39. Medicare is a federal health care program serving approximately 43 million elderly and disabled Americans.

40. The Medicare program is administered by the Centers for Medicare and Medicaid ("CMS") on behalf of the Secretary of Health and Human Services (the "Secretary"). CMS contracts with so-called "fiscal intermediaries," typically private insurance companies, to act as agents of the Secretary in administering the Medicare program.

41. In conformity with federal law, these intermediaries review claims to determine whether they are appropriate for reimbursement. Medicare "Part A," 42 U.S.C. §§ 1395*c*-1395*i*, provides insurance for covered inpatient hospital and related services. Medicare "Part B," 42 U.S.C. §§ 1395*j*-1395*w*, is a supplemental program insuring other items and services, such as out-patient hospital and physician services, supplies, and laboratory tests.

42. Broad wording excludes from Medicare coverage, "under part A or part B…any expenses incurred for items or services [which] … are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395*y*(a)(1)(A); *see also* 42 C.F.R. § 411.15(k)(l).

43. The Secretary is charged with the task of clarifying those services that are covered under the "reasonable and necessary" standard. 42 U.S.C. § 1395*ff*(a). Historically, the Secretary clarified this standard through less formal instructional manuals and letters, and held simply, as per the 1986 Manual Instruction, that medical devices not approved for marketing by the FDA are considered investigational and non-reimbursable. In 1995, the FDA, in conjunction with CMS, modified this general prohibition on reimbursement to allow payment by Medicare for IDEs classified by the FDA as "Category B" (non-experimental/non-investigational), where

all other approval and coverage requirements were met. (Such exception is not applicable in this case). In some instances fiscal intermediaries are authorized to provide local coverage determinations where such coverage is not otherwise excluded.

44. Experimental or investigational devices, however, have remained uncovered. The Code of Federal Regulations sets forth "Particular services excluded from coverage" excluding, *inter alia*, "experimental or investigational devices" which are not considered Category B, nor "furnished in accordance with FDA-approved protocols governing clinical trials." 42 C.F.R. § 411.15 (o); 42 C.F.R. § 405.201.

45. The CMS Intermediaries' Manual reflects this same coverage restriction. The Intermediary Manual provides, under "General Exclusions from Coverage," that "[m]edical devices which have not been approved for marketing by the FDA are considered investigational by Medicare and are not reasonable and necessary.... Program payment, therefore, may not be made for medical procedures or services performed using devices which have not been approved for marketing by FDA." Inter. Manual § 3151.1

46. Some reimbursement for unapproved devices is allowed where both the beneficiary and provider "did not know, and could not reasonably have been expected to know" the services provided were not covered by Medicare. 42 U.S.C. § 1395pp(a).

47. Additionally, when an otherwise approved medical device is *used* in an unapproved, off-label manner, the *use* is considered investigational and experimental, and therefore non-reimbursable. 42 C.F.R. § 411.15(o). Also, "Medicare payment is not made for medical and hospital services that are related to the use of a device that is not covered because CMS determines the device is not 'reasonable' and 'necessary'... or because it is excluded from coverage for other reasons." 42 C.F.R. § 405.207.

2. The Medicaid program

48. Medicaid, 42 U.S.C. § 1396, *et seq.*, is a public assistance program providing for payment of medical expenses for approximately 50 million low-income patients. Funding for Medicaid is shared between the federal government and state governments.

49. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines, and some services, such as inpatient hospital services, vaccines for children, and prenatal care, must be provided under the state program in order to receive federal funding. 42 U.S.C. § 1396*a*(a)(10). States may offer additional, non-mandatory services if they choose to do so.

50. Both federal and state law regulates the extent of coverage for medical devices, and their approved applications. Unapproved uses are typically excluded from reimbursement under Medicaid, as they are under Medicare.

3. Reimbursement under other federal health care programs

51. In addition to Medicaid and Medicare, the federal government provides reimbursement, in whole or part, for approved medical devices under several other federal health care programs, including, but not limited to, CHAMPUS/TRICARE CHAMPVA and the Federal Employees Health Benefit Program.

52. CHAMPUS/TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependents affiliated with the armed forces. CHAMPVA, administered by the United States Department of Veterans Affairs, is a health care program for the families of veterans with 100 percent service-connected disabilities. The Federal Employee Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for federal employees, retirees, and survivors.

53. The off-label use of biliary stent medical devices promoted by Medtronic is not eligible for reimbursement under any of these federal health care programs.

4. Direct purchases by federal agencies

54. In addition to reimbursement through Medicare, Medicaid, and other federal health care programs, the United States is a significant *direct* purchaser of medical devices through various federal programs. Medtronic's unlawful, off-label promotion of its biliary stents has resulted in taxpayer purchases of biliary stents for off-label vascular use by, for example, the following two government programs.

55. The Department of Veteran Affairs ("VA") maintains a system of medical facilities serving approximately four million veterans. The VA directly purchases medical devices that are utilized through its facilities and programs, including biliary stents.

56. The Department of Defense ("DOD") provides medical benefits to approximately eight million active duty personnel, retirees, and their families, and purchases medical devices such as biliary stents.

V. ALLEGATIONS

A. Medtronic Designs and Manufactures Its Biliary Stents for Off-Label, Vascular Use

57. Medtronic has fraudulently designed, manufactured, promoted and sold its assortment of biliary stent medical devices in contravention of federal law. Medtronic has marketed many brands of biliary stents: variously named BRIDGE, AURORA, ASSURANT, RACER, and the COMPLETE SE. FDA approval of each of these stents was fraudulently obtained in that Medtronic designed none of them for the single on-label use in the biliary system that was expressly submitted to and approved by FDA. Instead, each stent has been designed and promoted exclusively for off-label use in the vasculature.

58. Each of Medtronic's biliary stent products (with multiple model variations for vascular sizing) are indicated, *i.e.*, approved by FDA, for one use only - the "palliation of malignant neoplasm in the biliary tree." In lay terms, they are approved to treat, though not to help prevent or cure, cancer in the bile ducts and gallbladder by relieving the narrowing of the duct. As discussed above, these devices relieve obstruction and allow the bile duct to properly drain, thereby relieving some discomfort for patients. Biliary stents are commonly intended, and approved, for patients with advanced pancreatic cancer and little likelihood of survival. They are specifically *not* approved by FDA for any use in the vascular system. Despite this, and as detailed in what follows, Medtronic designs and promotes them for vascular use.

59. Despite clear knowledge of its illegality, Medtronic has explicitly designed and promoted its biliary stents for off-label, unapproved vascular use in the treatment, *inter alia*, of three common peripheral vascular conditions: renal stenosis (the narrowing of the major artery that supplies blood to the kidney, often elevating blood pressure), peripheral vascular disease in the superficial femoral artery ("SFA") (a disease of the blood vessels in the region of the femoral artery), and conditions requiring iliac artery stenting (iliac arteries being those that branch off the aorta).

60. As also discussed above, Medtronic has received 510(k) approval from FDA to market each of its biliary stent medical devices for one indication, *to wit*, the "palliation of malignant neoplasm in the biliary tree." Medtronic's biliary stents have received 510(k) approval based upon their similarity to previously approved biliary stents, which were themselves approved as a result of false and fraudulent submissions. They are recognized by FDA as Class II devices (Gastroenterology-Urology classification), subject to moderate regulation. Because the biliary duct does not access any blood vessels, there is far less safety

concern for their on-label use, as opposed to any use of the device in the vascular system which requires Class III regulation. Thus, the approval of new biliary stent devices for their accepted use in the biliary tree is far less rigorous than the approval process required to receive a new indication for vascular application. Medtronic chooses to forego this more rigorous and costly PMA process and instead fraudulently promotes its biliary devices off-label, contrary to federal law.

61. Medtronic forgoes compliance with Class III device approval by knowingly manufacturing and promoting biliary stents for vascular (Class III) use. This despite the clarity of federal law, and repeat warnings by FDA that such conduct is not lawful. On February 5, 1998, FDA, in a document titled "Guidance for the Content of Premarket Notifications For Metal Expandable Biliary Stents," stated that "...the only indication for these devices which can be approved under 510(k) is for palliation of malignant strictures in the biliary tree." Later, in 2003, FDA continued to warn Medtronic and other manufacturers by "remind[ing] them of their obligation to ensure that their devices are appropriately labeled for the way they are actually being used," noting that Medtronic and other biliary stent makers were directed to "obtain the necessary approvals for the specific vascular indications" they intend their products to address. The 2007 meeting between Medtronic and FDA, mentioned above, reinforced this long-standing concern of off-label design and marketing, and included further orders to discontinue unlawful practices immediately. None of these FDA warnings had any effect on Medtronic's behavior in the off-label development and promotion of its stents.

62. Medtronic accomplished this fraud on the Government, originally, by filing false 510(k) premarket notifications with the FDA, falsely certifying that the sole intended use for its Class II biliary devices was for application in the biliary tree as biliary stents. It so certified

because to disclose to FDA the actual, intended use and design of its biliary stents as vascular stents would result in a rejection by FDA of its 510(k) application, and a requirement to engage the rigorous demands of Class III device approval.

63. FDA-approved, Class III medical devices *are* available in the marketplace to address peripheral vascular conditions. Medtronic's competitors have spent, and continue to spend, time and money seeking FDA approval for vascular stent devices. For example, Cordis, owned by Johnson and Johnson, manufactures a stent for iliac and Gore manufactures a medical device for SFA. Other companies, such as Boston Scientific, manufacture similar devices. Medtronic has achieved an unfair competitive advantage, and increased risk to the public, by forgoing the Class III PMA process with FDA, submitting false and fraudulent certifications to FDA certifying that its stent devices were intended as biliary rather than vascular stents and aggressively promoting its "Class II biliary stents" for unapproved, off-label Class III vascular use. Further, as FDA has noted, the widespread use of biliary stents for unapproved vascular use limits the ability of manufacturers seeking approval from the FDA for such uses to enroll patients in clinical studies, since many patients and providers are already receiving biliary stents off-label due to off-label marketing by Medtronic.

1. Medtronic assigns Relator Mr. Dodd to finish commercialization of its RACER biliary stent for off-label vascular use

64. New to the peripheral vascular product line, Relator Enda Dodd arrived in Medtronic's Santa Rosa offices in September of 2003 as a Senior Research Manager brought to the United States to develop peripheral vascular products. Mr. Dodd was assigned to review and resolve possible quality issues on the RACER stent device prior to commercial release. Mr. Dodd was advised that the product had already received regulatory approval for release. In this project, Mr. Dodd reported to James Moriarty (Research Director), who reported to Tony

Semedo (VP of Research and Design). As his work began, Mr. Dodd discussed with Darren Hopkins (Senior Design Engineer), among others, the steps that needed to be taken to understand quality questions relating to RACER and thus position the product for release into the marketplace. The discussion centered upon stent integrity issues relevant to RACER's use as a vascular stent intended for renal procedures (*i.e.*, stenting within blood vessels connected to the kidneys).

65. As Mr. Dodd examined the design process employed and the product evaluations on file, a hybrid development strategy appeared. The design process implemented was governed by the "FDA Guidance For The Content Of Premarket Notifications For Metal Expandable Biliary Stents" while the sole and only commercial intent, as articulated by Trung Pham (Senior Product Manager) and others, was the treatment of stenosed (blocked) renal (kidney) arteries, a blood contact vascular indication. Additionally, the previously approved packaging specifications called up biliary device directions for use and product identification. Mr. Dodd was astonished to learn these facts.

66. Mr. Dodd met with Jeff Allen (Senior Design Engineer), the most experienced and senior stent design engineer in the Division, to discuss his concerns about the cracking issues relating to the stent's intended placement in a pulsating peripheral artery. Allen did not believe the product design as existed would be safe in the arterial vasculature. Mr. Dodd also spoke with Sarah Sheppard (Senior Regulatory Manager) who simply confirmed, as did Sara Toyloy (Regulatory VP - Vascular), that FDA's low threshold for Class II biliary device approval would be met by RACER and its then-current design.

67. Pham provided Mr. Dodd with the RACER Integrated Business Plan (IBP) which set out the business-directed process of a non-vascular FDA cleared indication while promoting

the new product offering exclusively for the treatment of renal artery disease. Pham went on to say that as the person charged with the commercialization of the RACER device, it was critical that it was competitive as a renal device whatever the purported basis for approval. Pham stated that Medtronic was projecting substantial sales and manufacturing build activity with related forecasts based upon expected sales of the device to interventional cardiologists. Pham went on to tell Mr. Dodd that Bill Hawkins (current CEO and then-Senior VP of Vascular Division) was exerting great pressure on the organization to build new revenue from peripheral vascular products and that any issues slowing release needed to be resolved immediately.

68. As part of his investigation, Mr. Dodd examined the record of biliary stent development at Medtronic over several years and was alarmed to learn that the entire biliary stent platform inventory was actually developed for vascular use, employing an unrelated biliary device FDA guidance as the basis of the development process, regulatory approval strategy and product identification. Despite the emerging details of fraudulent and false statements made to FDA, that is, that the devices were developed and to-be-marketed for biliary use only, Mr. Dodd was warned that this paradigm was driven by Hawkins acting himself on precedent established by past Divisional presidents including Scott Solano (CEO of AVE) and Andy Rasdall (past Division President).

69. The prior Medtronic biliary stents included the BRIDGE, ASSURANT, and AURORA stent platforms, all previously released employing 510k clearances which bore no relationship to Medtronic's intended commercial plans. Each of these stents were continuously promoted and marketed off-label as peripheral vascular devices, with vascular patient results and adverse clinical events forming key inputs to the ongoing product line development efforts. Each stent was approved by FDA based upon the same type of fraudulently submitted Pre-

Market Notification statement used to procure approval of RACER. That is, each successive submission transmitted to FDA by Medtronic falsely certified the company's intentions and subsequent commercial actions.

70. Both orally and in writing, Mr. Dodd objected often and strenuously to the dysfunctional design process arising from the fraudulent submission procedures that Medtronic intended to use, leading to a hybrid 'off-label vascular device product design' that would be submitted to FDA for approval solely as a biliary stent. Renal stenting was the obvious, true clinical indication for RACER, not the FDA-applied-for indication of biliary use. Mr. Dodd's emerging objections to this situation were immediately rebuffed with Mr. Dodd being alternately counseled or threatened about opposition to the scheme.

71. During Mr. Dodd's three-year tenure at Medtronic's vascular headquarters, he expressed his concern and objections to the highest levels of Medtronic, including to, among others, Bill Hawkins (current CEO and then Senior VP), Tony Semedo, Chris Hadland (VP for Quality), Kim McEachron (VP Human Resources), Vivek Jayaraman (Senior Business Director), and Jay Radovich, Ph.D., (Senior Dir. of Research and Design). Mr. Dodd's concerns and reluctance caused delay, and increased cost, in the roll-out of RACER. Mr. Dodd learned that his precaution and objection to the fraudulent FDA scheme was not appreciated by management. This was communicated first to Mr. Dodd through Moriarty. Moriarty himself was involved directly in resolving issues surrounding patient injuries related to the ASSURANT stent (itself promoted off-label), and was then being intensely pressured to enact the fraud. He cautioned Mr. Dodd (as a friend and supervisor) that his conduct, however praiseworthy, was not well tolerated by management. Moriarty was ultimately pushed away from his research portfolio in Santa Rosa due to his reluctance to follow commercial imperatives over patient considerations.

72. Eventually, in November of 2003, the RACER stent, like its predecessors, was approved by FDA on the heels of Medtronic's fraudulent 510(k) Pre-Market Notification Application for biliary stent clearance. FDA cleared RACER for release "subject to" certain "limitations," particularly that "[t]he safety and effectiveness of this device for use in the vascular system has not been established." FDA also required that the sole indication for "BILIARY" use be prominently displayed on promotional materials for the RACER stent.

73. Medtronic's own product launch IBP Executive Summary for RACER makes abundantly clear that the company always intended this device to be made and promoted for off-label vascular use. "Racer is Medtronic Vascular's fourth entry into the renal stenting segment," which is, "forecasted to generate $4.25M in revenue for FY04 and $13.44M for FY05." The "renal stenting segment" is entirely, 100% off-label for Medtronic, and these forecasts for RACER were predicated necessarily upon off-label sales of this purported "biliary" stent. The then-recent PMA approval of the superseded 'BRIDGE Extra Support' stent device was now deliberately rendered obsolete in favor of the heavily marketed cobalt chromium RACER stent. This cannibalization was built into the sales pitch as a means of generating false clinical credibility for the new unapproved renal device. The Executive Summary goes on to explain that this device should cannibalize predicate biliary stents the company manufactured (*e.g.*, BRIDGE, ASSURANT), devices which were also designed and sold for off-label vascular use.

2. Medtronic retaliates against Mr. Dodd for his opposition to the development of the COMPLETE SE biliary stent for off-label vascular use

74. Medtronic more recently obtained through fraud a 510(k) approval for its COMPLETE SE (Self-Expanding) biliary stent. This device received marketing clearance from FDA on November 15, 2007, after Medtronic falsely certified that it was intended for use as a "substantially equivalent" device to existing biliary stents, *i.e.*, exclusively for use in the "biliary

tree." Like other biliary devices, it was reviewed by FDA's Gastroenterology/Urology classification and review committees. These committees would not have even reviewed this device had Medtronic disclosed its intended design and use of this stent for the vascular system. Medtronic would not have received its premarket clearance had the intended use of the device been disclosed, rather than concealed, and had it not falsely certified to the contrary. Medtronic's actions render all of its biliary stents misbranded, adulterated and ineligible for reimbursement.

75. Mr. Dodd was personally assigned to work on product development for the new COMPLETE SE stent following his work on RACER at the close of 2003. At a meeting in March 2004, Medtronic's Product Review Committee, including Mr. Dodd, discussed the development of this new stent. CEO Hawkins led the discussions, with most of the Division Board present. At that meeting, convened to discuss the overall plan for the COMPLETE SE, a regulatory strategy to seek both biliary and vascular approval for the COMPLETE SE was explained to Hawkins by regulatory executives. This was important and unprecedented because Medtronic had never sought vascular approval for its stents in the past as a precursor to legitimate commercial operations. Amy Conuel (Regulatory Director -Vascular Division) described FDA requirements for this dual-purpose approval process. Given his experience with RACER, Mr. Dodd was skeptical that the company would follow through on this approach. After the meeting, Mr. Dodd approached Hawkins himself following these discussions and asked "Will you support this project," to which Hawkins responded, "Do you doubt me?" As it turned out, Mr. Dodd had every reason to doubt Hawkins, who eventually abandoned the stated desire to seek proper vascular approval for Medtronic's new device.

76. Following his conversation with Hawkins, Mr. Dodd remained skeptical, and discussed his concerns in the weeks that followed with Moriarty, Semedo, and Alan Milinazzo (VP of Coronary and Peripheral), as well as other senior executives. As Dodd understood, the FDA was clear that it wanted companies to spend the resources to ensure public safety in obtaining proper Class III device approval for any stents manufactured with intent to be used in the vasculature. Mr. Dodd was not comfortable replicating his experiences with the RACER stent, and now had the knowledge to actively push for Medtronic to comply with FDA regulation. Others were less hopeful. Following the March 2004 meeting, Senior Design Engineer James Mitchell, who reported to Mr. Dodd, sought transfer to the Endovascular Group, confident that management would not follow through on its commitment to properly seek Class III device approval for vascular use.

77. Aware of increased FDA scrutiny, Medtronic acted more subtly regarding its off-label stent development for the COMPLETE SE, though slowly moving away from its earlier-stated plan to seek vascular approval. In 2004 the initial Integrated Business Plan for COMPLETE SE was circulated by Pham to Mr. Dodd and various executives for comment. Mirroring, largely, the IBP for RACER, the document spelled out the off-label vascular intent of the device. A substantial rewrite was directed so as to avoid the obvious emphasis on what would become fraud on the FDA. Pham himself was later replaced. For the balance of 2004 and in the years to follow, Dodd was systematically deprived of the resources necessary to develop a Class III vascular stent that would pass FDA requirements. Funding for vascular indications, PMA testing and clinical work (all necessary for FDA approval of a vascular stent) were eliminated by Jayaraman under the direction of Hawkins, who continued to show direct interest in the COMPLETE SE project.

78. Finally, in a meeting on the COMPLETE SE in the summer of 2005, Jayaraman stated plainly that Medtronic would no longer be seeking vascular approval for the device. The management team developed Product Launch Plans for the launch of COMPLETE SE that were predicated entirely upon revenue forecasts from off-label sales of the device. All regulatory and clinical funding requests associated with a vascular PMA (the only lawful approach Medtronic needed to take in light of its true intent) were simply refused. Jayaraman used the subsequent product development process (PDP) phase reviews to institutionalize his decision and move the business increasingly away from legitimate commercialization. As the prospect of a vascular indication receded, aggressive plans to achieve 510(k) biliary clearance were not accompanied by any efforts to commercially promote this putative on-label use.

79. Dodd protested the decision to again, as with RACER, fraudulently seek Class II device approval as a biliary stent, Medtronic's newest vascular stent designed and intended for vascular use. Even prior to Jayaraman's statement that the company would no longer even pretend to show interest or fund clinical study for vascular approval prior to launch of COMPLETE SE, Mr. Dodd discussed it with, among others, David Garcia (Senior Regulatory Specialist). Garcia informed him that nothing could be done, and that Mary Edwards (then VP of Vascular Regulatory) assured him that the same off-label practice had been successfully undertaken at C.R. Bard, her previous employer, and could not successfully be challenged in the company. Subsequent email communications regarding the COMPLETE SE, between Mr. Dodd, Edwards, Conuel, and others, make clear that Medtronic's regulatory team could not and would not stand in the way of business management's determination to get the COMPLETE SE to market through false statements in a 510(k) application falsely suggesting biliary rather than vascular intent.

80. Realizing he could not succeed in getting Medtronic to reconsider its abandonment of the once-stated plan to properly seek vascular approval, Mr. Dodd made efforts to subject the development plans for the device to rigorous testing requirements such as would be required for vascular approval. In September of 2005, Jayaraman (in a crowded bar) informed Mr. Dodd that Medtronic was "on to him," and that he would see to it Dodd was fired. In April 2006, Jayaraman began to make good on his threat, and Mr. Dodd was removed from his team leadership position on the COMPLETE SE. Mr. Dodd was characterized by Jayaraman as a person "intent on ruining the business" and the "livelihood of the peripheral vascular sales people." Mr. Dodd was put on a "clock," meaning he was told to find a new job and provided with outplacement services.

81. In the summer of 2006, Christopher Fang (formerly Director of Clinical Affairs) refused to re-approve the project's clinical plan, stating to Mr. Dodd that it was a sham (since no legitimate clinical studies were going to be completed as part of the FDA application for COMPLETE SE). Under Jayaraman's direction, Jay Radovich (then Research Director) threatened Fang to make him sign off on the re-approval, and eventually Fang was pressured out of Medtronic.

82. Also that summer, Medtronic took advantage of the annual Vascular Interventional Advances Conference (VIVA) to promote its newest off-label device. VIVA is a significant annual opportunity for Medtronic to promote its biliary stents off-label to a massive gathering of vascular physicians. According to its website, VIVA is "dedicated to advancing the field of vascular medicine," and includes Medtronic as a commercial supporter.[7] In the weeks preceding the 2006 VIVA training conference, Hawkins personally reviewed the progress of the

[7] *See* www.vivapvd.com, last accessed February 15, 2010.

COMPLETE SE in Santa Rosa. Hawkins complimented Jayaraman and Radovich for "correcting" development issues (*i.e.,* eliminating those persons who stood in the way of the expected fraudulent 510(k) application for the intended vascular device), and noted that the next step was to "fix the field issues" (*i.e.,* train and prepare the sales reps to promote the device for vascular use upon its completion and 510(k) approval). Medtronic then used VIVA to present its expected-for-approval COMPLETE SE to the vascular community. Mr. Dodd was prevented from attending VIVA, but many others from the technical team did attend. They confirmed that the total marketing effort at VIVA focused upon the expected 510(k) clearance and imminent availability of the COMPLETE SE for U.S. vascular disease treatment. At this time, there existed no genuine plan to promote the COMPLETE SE internationally.

83. On the heels of its summer 2006 agreement to pay $40 million to settle charges related to its illegal kickbacks to doctors in promotion of its spinal products, Medtronic executives including Jayaraman continued active vascular promotion of its coming "biliary" stent. A COMPLETE SE US Sales Training promotional video was created by Medtronic to showcase the off-label vascular application of the device, and the roll-out plans for the device were detailed to its vast sales force. At the TCT (Transcatheter Cardiovascular Therapeutics) show in October of 2006 (a well-attended vascular conference for the Product Development and Manufacturing Industry) Jayaraman and others promoted COMPLETE SE to cardiologists. Ironically, Donna-Bea Tillman (then Director of CDRH's Office of Device Evaluation) told manufacturers of biliary stents at the Conference, "we know that this is going on," referring to the off-label promotion of biliary stents for vascular use, and that FDA is "particularly frustrat[ed]" that "big companies, who in my mind, should know better," were also "doing it."

84. During the final months of 2006, Conuel (Regulatory Director) was placed under intense pressure by Medtronic to continue down the path of a fraudulent 510(k) submission for the COMPLETE SE. In December 2006 a meeting was convened to address Conuel's concerns that the regulatory team was being bullied by Radovich and others. At the meeting, Conuel described that these actions were adversely affecting the ability of her group to appropriately execute FDA quality system requirements, thus jeopardizing their compliance efforts. Conuel reiterated the legal requirements, repeated by FDA, that these devices must be submitted for vascular approval where intended for vascular use. This meeting was attended by Jayaraman, David Garcia and others from both the regulatory and business sides of Medtronic Vascular. Conuel's concerns gave Medtronic no pause. Conuel was subsequently forced from the company (after nearly a decade) in 2007, subsequent to the eventual retaliatory termination of Mr. Dodd.

85. Medtronic ignored, retaliated against, and otherwise intimidated those within the company who objected or expressed reservations about the ongoing illegality or impropriety of seeking 510(k) approval for stents designed and promoted for vascular use. Medtronic fraudulently obtained FDA approval of its COMPLETE SE biliary stent in November of 2007.

3. Medtronic promotes its biliary stents to vascular specialists, not physicians who use biliary stents on-label

86. In addition to Medtronic's design and marketing of biliary stents for off-label vascular use, Medtronic also engages the vascular medical community to promote and observe the efficacy of its biliary stents in their intended vascular applications. During his years at Medtronic, Mr. Dodd was aware of multiple visits to clinical sites (typically hospitals) by Medtronic engineers and other employees, including Pham, Mitchell, and Matthew McCarthy

(Senior Product Manager), all of which were to observe vascular implantation of its devices. Never were visits made to observe biliary application of the company's so-called biliary stents.

87. All clinical advisory meetings, VIP doctor visits, sales trainings and related promotional and training videos and other materials focused exclusively on the practice of vascular implantation of its biliary stents. Mr. Dodd regularly observed dozens of physicians visiting Medtronic's Santa Rosa offices to discuss vascular use and application of its stent products.

88. No one on the vascular commercial staff had any knowledge of, nor sought to acquire any knowledge of, the practice of bile duct stenting (the only FDA-approved use for Medtronic's biliary stents). Nor was there any familiarity with the distribution channels or physician practice groups associated with the on-label use of the devices. Medtronic excluded any funding to facilitate contact between the hypothetical biliary stent design teams (or anyone else in the company) and the gastroenterologists who would ostensibly use these devices for their on-label, biliary indication. Medtronic promoted its biliary stents off-label to cath labs where they would be utilized exclusively by physicians practicing in the vascular arena, using expensive C-arm x-ray systems to permit the precise placement of these biliary stents into the highly complex arterial vasculature.

89. Medtronic also used Clinical Advisory Boards (CABs) to push its biliary stent products into the vascular community. These boards were made up of influential peripheral vascular physicians in the U.S., who were urged and enticed by Medtronic to promote and use its devices off-label, and to train others in the medical community to do the same. At conferences like VIVA, TCT, and others, Medtronic made efforts to maximize the impact of these influential physicians. With dinners and other inducements, Medtronic attempted to get physicians excited

about its line of off-label vascular products. It was well-known at the company that such treatment of physicians was commonplace.

90. Mr. Dodd himself attended one CAB meeting held in Miami in January of 2005, where, led by Jayaraman, Medtronic discussed the vascular use of its purported biliary stents with vascular physicians. Lavish hotels, expensive meals and poolside service were provided by Medtronic to the physicians in attendance. Milinazzo, Semedo, and other Medtronic management were also in attendance at that meeting. Conveniently, this meeting was held the day before these same influential physicians would moderate the International Symposium on Endovascular Therapy (ISET) conference, a conference where Jayaraman and others continued off-label promotion of Medtronic's stents.

91. Still, there has been growing concern even among these Medtronic-friendly physicians that the continuing lack of clinical data in support of vascular use for these devices needed to be corrected by Medtronic. At the last CAB meeting Mr. Dodd attended, in the summer of 2006, a prominent vascular physician told Medtronic that it needed to swiftly shift over to "evidence-based medicine" and obtain "legitimate" indications for its stent devices. Medtronic ignores these voices in the medical community, just as it has ignored the FDA, and its own employees' expressions of concern.

92. All of the aforementioned conduct has been in obvious violation of FDA law governing medical devices, and also in violation of the False Claims Act. Medtronic engages in this fraud because it is enormously more lucrative to do so. The industry-wide ratio of on-label biliary stent procedures as compared to peripheral vascular procedures is on the order of 1:250. The on-label market for biliary stent use is simply dwarfed by the market Medtronic creates for off-label vascular use of its biliary stents. The peripheral artery diseases addressed by off-label

application of biliary stents to the vasculature predominantly effect millions of older Americans, many of whom rely upon Medicare or Medicaid for their healthcare. CMS data indicates that roughly 80% of the payments for purchase and use of medical devices are publicly funded by Medicare and Medicaid. Federal and state Governments have spent tens of millions of taxpayer dollars on Medtronic's off-label biliary stents, none of which is authorized by law.

B. Medtronic Dissolves its Peripheral Group and Shifts its Off-Label Activity to the CardioVascular Division

93. Medtronic has developed and marketed hundreds of medical devices intended to address a variety of medical conditions and procedures. Various divisions within Medtronic are responsible for promotion and marketing of the company's numerous devices. Until early 2007, Medtronic maintained a Peripheral Products Group, engaged, *inter alia*, in the off-label promotion of Medtronic biliary stents. That group was conspicuously dissolved in 2007, following Medtronic's meeting with FDA on off-label promotion of stents, and its workforce absorbed into a new division. Jayaraman, who attended the FDA meeting, oversaw the systematic removal of evidence of the company's off-label conduct within the Peripheral Group and otherwise. Prior to its dissolution, the Peripheral Group was responsible for the promotion of peripheral products, again, those products that address conditions within the circulatory blood system outside of the heart. The vast majority of peripheral product sales unlawfully consist of biliary stents.

94. In its place, in 2007, Medtronic created the Medtronic CardioVascular (or "Vascular") Division. Responsibility for off-label biliary stent promotion moved into this Division. The Vascular Division is broadly responsible for development and promotion of products that treat conditions related to the heart and circulatory systems. Such products include various stents and catheters (hollow tubes typically inserted into a body cavity duct or vessel).

Both the stents and catheters promoted by Vascular are used for treating coronary and peripheral vascular conditions, as applied in various medical procedures.

95. Within the CardioVascular Division are both the Endovascular Group and the Coronary Group. The Endovascular Group primarily promotes the use of non-coronary medical devices "within a blood vessel," and its primary medical device is the AneuRx AAAdvantage Stent Graft System ("AneuRx") used for the treatment of Abdominal Aortic Aneurysms. More recently Medtronic Endovascular has marketed the Talent Abdominal Stent Graft for treatment of these aneurysms. An aneurysm is a bulge that forms within the wall of a blood vessel, typically from an accumulation of fatty deposits on the vessel wall. With time, the force of normal blood pressure in the aneurysm can lead to a rupture. When the aneurysm forms in the aorta, one of the body's main blood vessels extending through the abdomen, it is called an abdominal aortic aneurysm. For many patients, a substantial risk exists that such an aneurysm will burst, potentially causing death.

96. The AneuRx medical device is offered by Medtronic as an alternative to conventional surgery to address these aneurysms. A procedure known as "endovascular stent grafting" involves placement of the AneuRx stent graft, a woven polyester tube covered by a metal web, inside of the diseased vessel without opening the surrounding tissue. When done properly, the stent graft excludes the aneurysm from normal blood flow, thus preventing rupture.

97. Medtronic's Coronary Group develops and promotes, according to its company website, "a full line of products for use in the diagnosis and treatment of coronary arteries that are restricted or blocked by atherosclerotic plaque. Primary products include coronary stents (for both smaller and larger vessels), guide catheters, balloon catheters, diagnostic catheters and

guidewires." Coronary arteries, termed such because they encircle the heart in the shape of a crown, are the vessels that supply the heart muscle with blood rich in oxygen.

98. Among the Medtronic products promoted for approved use by the Coronary Group are the Driver Coronary Stent System and the Micro-Driver, both "bare-metal" (as opposed to "drug-eluting") stents for use by interventional cardiologists in treating patients with symptomatic ischemic heart disease. The Coronary Group also sells approved catheters and guidewires for use by cardiologists treating heart patients.

99. In addition to encouraging the sale of Medtronic's aforementioned cardiovascular-related medical devices, Medtronic requires, and has required, its sales representatives ("sales reps") in both the Endovascular and Coronary Groups to promote and sell its "peripheral products." Again, peripheral products are those devices intended for application in the vascular system, outside the heart. Biliary stents (promoted for vascular use) are the biggest part of Medtronic's peripheral product inventory – albeit off-label and unlawful.

100. Medtronic requires the off-label promotion and sale of these stents as peripheral products with full knowledge that the vast majority of its peripheral product sales come from the sale of biliary stents for unapproved, off-label uses. Medtronic is also aware that its promotion of such uses is unlawful. As detailed below, sales representatives in both the Endovascular Group, such as Relator Ms. Tricia Nowak, and the Coronary Group have been relentlessly instructed to sell peripheral products, and financially punished or rewarded based upon such sales, in contravention of federal law, and explicit FDA warning.

101. These sales groups have been directed for years, from the top of the company down through regional and territory managers, to work as a vascular sales force for the promotion and sale of thousands upon thousands of biliary stents never intended to be used on-

label. They are marketed and sold to cardiologists, radiologists, and vascular surgeons who perform or participate in surgeries whereupon these stents are placed into a patient's vascular system. Prominent vascular surgeons are invited by sales reps to join Medtronic's Clinical Advisory Boards, discussed *supra*, where they receive a "fee" for their attendance and participation in off-label discussion of biliary stents. In addition, Medtronic sales reps facilitate sponsorship of "VIP" physician meetings at which vascular surgeons (recruited by sales reps and senior Vascular Division executives) listen to presentations by other doctors, and often Medtronic employees, on the off-label use of biliary stents. The doctors whom Medtronic targets do not work in gastroenterology, and never use these biliary stents for their exclusive, approved use in the bile duct.

102. Quite simply, in order to hide its explicitly off-label peripheral promotion through a Peripheral Group that unlawfully marketed biliary stents for years, Medtronic has attempted a more disguised means of promotion by adding these off-label sales and VIP/CAB recruitment responsibilities to the job requirements of altogether different sales groups with the Vascular Division.

C. Medtronic Unlawfully Instructs its Sales Reps to Promote Unapproved Sale and Use of Biliary Stents for Vascular Application

103. The off-label development of Medtronic's biliary stents was known and approved by Medtronic CEO Hawkins (formerly head of the Vascular Division, the locus of the fraudulent conduct's genesis), Jayaraman, Scott Ward (Vascular Division President), Tony Semedo (now VP & General Manager of Endovascular Innovations), Sean Salmon (VP and General Manager) and many others. Mr. Dodd has direct knowledge that CEO Hawkins personally reviewed and endorsed the efforts to design and commercialize biliary stents for off-label promotion, and direct knowledge of the involvement of many others. With reported industry-wide U.S.

peripheral vascular sales in 2005 of nearly $1 billion, Medtronic was unwilling to comply with medical device law or pursue the expensive process of Class III device approval for its intended vascular stents.

104. Medtronic's peripheral vascular business has reflected a near total dependence upon off-label promotion of biliary stents in order to reach revenue targets in its annual financial operating plans, including its 2005 vascular revenue plan which projected millions in off-label sales to satisfy revenue expectations. One set of promotional materials given to sales reps titled "Medtronic Peripheral Solutions" highlights and describes the features of each of its biliary stents, including the "COMPLETE SE" with "Anticipated Launch Fall 2006."

105. Tellingly, Medtronic does not promote, and has not promoted, biliary stents for their *approved* use in the biliary tree. Medtronic does not maintain a sales force to sell biliary stents for their approved use. It does not market to physicians practicing in the area of medicine that uses biliary stents for their sole approved use. Medtronic designed its purported biliary stents as vascular stents, fraudulently sought 510(k) approval for them as biliary stents rather than vascular stents, and has exclusively manufactured, promoted, and sold these devices for use as off-label vascular stents.

106. An e-mail from Medtronic's Peripheral Group Marketing Manager, David Moeller, subsequent to Medtronic's 2007 meeting with FDA, reminded sales reps to "destroy" all promotional materials for its biliary stents because the materials explicitly promoted them *as* "peripheral devices." For example, in its brochure for the Racer Biliary Stent System, Medtronic advertised its product in prominent text as "the first cobalt chromium stent launched for *peripheral applications*...." (emphasis added). Moeller included as an attachment to his email the Peripheral Product Catalog including "all of the product codes and specs for biliary stents,"

so that sales reps could continue off-label promotion without interruption, even without the incriminating brochures. Medtronic's promotion of biliary stents for peripheral use is widespread, unabashed, and unabated. And its attempts to cover up this fraud only further illustrate its culpability.

107. Though each of its biliary stents is considered by the company to be a "peripheral device," marketed and promoted for use exclusively in the vascular system and recorded within the company as a peripheral product, Medtronic does not list these devices under the "Peripheral Products" section of its website.[8] Sale of biliary stents constitutes the vast majority of Medtronic's multi-million dollar peripheral product revenue, as it has for years, yet it pretends on its website (monitored by the FDA) that such products do not even exist. Despite this pretense, Medtronic in fact keeps constant track of the "peripheral sales," mostly biliary stent sales, each of its Vascular sales representatives makes.

1. Relator Ms. Nowak and the rest of the Vascular sales force is directed to promote and sell biliary stents for off-label vascular use

108. Medtronic keeps meticulous track of its off-label biliary stent sales. In an e-mail sent March 17, 2008, to Medtronic's Endovascular "Desert" regional sales force, Endovascular Regional Manager Lowery Gay (then Ms. Nowak's supervisor) informed his sales team that "15 Complete SE units" were available for sale, that they needed to "utilize this allotment to get sales this quarter," and that "[i]f anyone has any SFA cases upcoming please let [sales rep] Danny [Lewis] know so he can get the units to you." The COMPLETE SE, like the other biliary stents in Medtronic's inventory, is not approved for use in SFA cases – but it is promoted for such use nonetheless, and despite FDA instruction not to do so. A November 1, 2007, e-mail to the U.S. Sales Team, from Amit Rushi (International Marketing Manager, Peripheral Marketing)

[8] *See* www.medtronic.com/physician/vascular/index.html (last accessed February 15, 2010).

informed sales reps that "Stenting is established as the standard of care in the SFA." Albeit, Medtronic has no approved stent for use in SFA medical procedures, only unapproved biliary stents. These two exemplars of off-label communications are barely the tip of the proverbial off-label promotion iceberg at Medtronic. The off-label promotional and compensation schemes advanced by Medtronic are national in scope, across all of its regions and sales territories.

109. Medtronic's "Endovascular Sales Representative FY08 Compensation Plan Communication," dated May 2007, lists as a "Key Priority for Endovascular" that the Group "[c]ontribute to the success of Peripheral Product sales." "Peripheral Commissions" are included in the sales rep compensation plan, as are "peripheral bonus[es]." Peripheral sales by sales reps are tracked throughout the year, including which biliary stents are sold by which sales reps and to whom, and sales rep rankings (upon which compensation is based) are calculated, in part, based upon figures derived from peripheral sales.

110. Medtronic has maintained a "Summit Quest Contest" for its Endovascular sales reps, including Ms. Nowak. The "objective" of the contest is to "recognize and reward the 3 Sales Representatives who achieve peak performance each quarter." Awards worth several thousand dollars are given to the sales representatives responsible for the highest revenues from sale of Medtronic devices. Primarily, sales reps within the Endovascular Group are responsible for promotion of the AneuRx device (discussed *supra*), and related endovascular medical devices. Medtronic, however, requires that each sales representative "must meet or exceed your Peripheral number to participate" in the contest. The minimal peripheral quota is $10,000 in sales per quarter. In other words, no matter how many approved devices a sales rep sells in a given quarter, he or she is not eligible for this financial incentive unless meeting a target for mostly off-label, unapproved sale of peripheral devices.

111. Brad Baxter, Area Director for Endovascular Innovations (and Lowery Gay's supervisor), in a January 23, 2008, e-mail to Ms. Nowak, forwarded the then-most-recent Summit Quest Rankings, which highlighted the top three peripheral sales reps each of whom sold numerous off-label biliary stents (a list that did not include Ms. Nowak who refused to promote stents off-label), and asked, "Tricia, So are you going to make a move to ruin someone's day? Which accounts do you sell peripheral stents to? Lowery use [sic] to make a living off peripheral I am sure you two can develop a plan." This type of subtle, and not so subtle, pressure to unlawfully promote and sell biliary stents for off-label use is commonly used by Medtronic management.

112. An e-mail dated February 25, 2008, from Gay, Ms. Nowak's manager, to his sales force, applauded the efforts of sales reps who were accomplishing peripheral sales, "Congrats to Debbie, Danny, and George for getting on board with peripheral this quarter. I would like to see every rep represented with sales this quarter. Let me know what help/resources you need."

113. Sales reports frequently circulated to the Vascular (again, both Endovascular and Coronary) sales force illustrate that the vast majority of peripheral product sales consist of Medtronic's biliary stents sold for off-label use. In the Fourth Quarter of Fiscal Year 2008 (Feb-March-April), Medtronic's Coronary and Endovascular sales reps earned Medtronic over $4.2 million in "Peripheral Sales," the vast majority of which were for the off-label sale of biliary stents. Over $15 million in mostly off-label sale of biliary stents was reported for fiscal year 2008. Sales of $4.7 million were reported for the First Quarter (May-June-July 2009) of Fiscal Year 2010. These reports on peripheral sales (which detail every sales transaction and are sent to every Coronary and Endovascular sales rep) illustrate with clarity that both groups are engaged in significant promotion and sale of biliary stents for off-label use. The reports show that

although a limited number of peripheral sales are for approved Pioneer catheter systems, all across the United States most sales are for biliary stents. It is also important to note that the Pioneer system was *not available for sale* during most of fiscal year 2007 (though Ms. Nowak, with others, was misleadingly informed by Medtronic management that requiring peripheral sales was legally compliant because *some* devices within the peripheral unit, *i.e.*, Pioneer, have been approved).

114. Each sales report sent to Ms. Nowak and the rest of the Vascular Division during her years at Medtronic showcased the ongoing success of off-label promotion and sale of biliary stents. Every report includes a summary listing the Regional Manager, region, territory, sales rep, the number of devices sold, and the net revenue from each sales rep's efforts for the given fiscal quarter. By way of example, in 3Q of FY09, sales rep Brad Moulds (of the Coronary Group) sold 164 peripheral devices, worth nearly $150,000. The vast majority of the peripheral products sold by Moulds were off-label biliary stents – AURORA, RACER, ASSURANT, and COMPLETE SE. This off-label sales achievement is rewarded by Medtronic with additional financial compensation, as per the annual Compensation Plan for sales reps, which includes a percentage bonus for all off-label biliary device sales.

115. Each sales report also includes a spreadsheet of every hospital or company that purchased these products, when they were purchased, the price of purchase, and the product number for every device. During the fiscal quarter referenced above, Moulds sold approximately 75 biliary stents to Kansas Heart Hospital alone. In 2Q of FY09 Endovascular sales rep Salvatore Sparacino sold more than a dozen COMPLETE SE biliary stents to Access Inc., a healthcare management company specializing in vascular procedures. These are but two

examples among thousands. Medtronic places a priority on monitoring the details of its off-label biliary stent promotion, and incentivizes its sales force to motivate them for further sales.

116. The unlawful promotion and sale of biliary stents for off-label use is recognized and appreciated by Medtronic management. An e-mail from an Endovascular Group sales representative, Danny Lewis, to management and colleagues, dated September 21, 2007, expressed satisfaction in the successful sale and application of biliary stents, "two Aurora's and an Assurant," for off-label use by a cardiologist in addressing an iliac occlusion. The e-mail continued, "I know that working with Cardiologists has been somewhat taboo in our business for some time, but by using a combination of data, relationships, and some of the other tools in our bag, these practitioners can, and should, become our allies over time."

117. Rather than responding with words of caution about off-label promotion of biliary stents, Area Director Baxter responded with thanks for the "excellent use of resources," "[a]wesome to see you supplying MDT [Medtronic] stents for Pioneer procedures – you would be surprised how often it is overlooked. It is as important to provide stents for Pioneer as it is Reliants for AAAdvantage cases." Baxter closed with praise – "Danny, excellent job." Such praise explicitly encourages the promotion of biliary stents for unapproved vascular use.

118. By contrast, Ms. Nowak, who refused to promote biliary stents off-label, was constantly reminded of her company obligation to do so. Gay sent Ms. Nowak an e-mail on July 8, 2008, suggesting "a great opportunity to get your foot wet in Peripheral. We could showcase the Pioneer as well as the Complete SE" at an upcoming symposium. Ms. Nowak's FY08 evaluation, while praising her "tremendous sales year," stated plainly that "[i]n FY08 the peripheral business was non existent. There is an expectation to sell the peripheral portfolio and that will be an area of focus in FY09." In other words, off-label sale of biliary stents is an

"expectation" of Medtronic's sales force, no matter how stellar their on-label sales otherwise. As Gay told Ms. Nowak – "It's not your call not to sell peripheral."

119. Because Gay and other regional managers were also pressured from higher management to have *their* sales force reach certain peripheral sales numbers, these managers increased pressure on their sales reps to move these products off-label. In an email to his regional sales force, on July 11, 2008, Gay wrote "Our Peripheral business in Q1 is a little light. We have only 41k booked and 20k is from Danny. I would like everyone to give me your Peripheral forecast for Q1. Please respond back to this email with how you will finish Q1 in Peripherals. I am willing to make some aggressive deals on COMPLETE SE's or any other stent. Let's close strong on peripheral as well."

120. On November 25, 2008, Gay provided his team a synopsis of the morning's sales conference call, which included a section on Peripheral – "Selling Peripheral is an expectation of every eligible rep. The expectation is 10K per rep per qtr." Among the products noted, "[w]e have a selection of Biliary stents: Racer, Assurant and Complete SE."

121. The Coronary Group is additionally given a peripheral quota to reach, despite their explicit responsibilities to promote and sell coronary medical devices. In September of 2007, sales reps in the Coronary Group were provided "FY'08 2nd Quarter Targets" which included significant peripheral numbers in the thousands of dollars. These targets determine the compensation given to a sales representative within the Coronary Group, just as they do the Endovascular Group. On June 11, 2007, the sales reps in the Coronary Group were provided a "peripheral quota," reminding them of their obligation, like that of the Endovascular sales reps, to sell and promote biliary stents off-label. Peripheral sales reports indicate that the Coronary

Group generates far more revenue from off-label sale of biliary devices for peripheral use than does the Endovascular Group, at a rate of approximately 7 to 1.

122. In addition to requiring all CardioVascular Division sales reps to unlawfully promote biliary stents as a condition of their compensation, Medtronic also asks these sales reps to attend peripheral training with practicing physicians in fields of medicine for which biliary stents are unapproved so the reps can sell biliary stents with greater knowledge of vascular applications. Medtronic asks its sales reps to encourage their client physicians to attend these trainings, thereby creating market demand for off-label use of their biliary stents. Also, one-on-one peripheral preceptorships on vascular procedures, promoted by Medtronic and ostensibly run by HealthStream (a NASDAQ company offering education and training in the medical device industry) team up Medtronic sales reps with practicing vascular physicians. Emails, such as one sent September 25, 2007 to the Coronary and Endovascular groups, promote participation in these programs as a method of learning off-label peripheral application of Medtronic stents, and list the physicians and clinical locations participating in the training.

123. For example, in a September 11, 2007, e-mail Debbie Shaver, then-Director of Key Accounts in the Vascular Division (subsequently promoted to Director of Training and Education), wrote Medtronic's Endovascular Regional Managers, informing them of peripheral training "led by a surgeon and cardiologist" that "cover[s] common peripheral interventions, *i.e.* renal, iliac, SFA." Sales reps are promised to be instructed on "what size devices to use along with ancillary equipment selection." John Smeltzer (Regional Sales Manager) forwarded this along to sales reps, with cc to Baxter, describing the "great opportunity for YOU, yes YOU, to get some hands on peripheral training" to "enhance your ability to talk with your customers about the details of this type of procedure." Similar e-mails are frequently sent. Medtronic

trains its vascular sales reps on unapproved vascular applications for biliary stents approved only for use in the biliary tree. Medtronic also encourages its sales reps to attend peripheral device seminars – one "high importance" e-mail informed sales reps of the "11th Annual Peripheral Vascular Update" in San Antonio, Texas and the "Management of Vascular Disease Conference" at the Four Seasons in Boston.

124. Pursuant to a Medtronic "fellows" program for physicians, Medtronic disseminates a registration form inquiring, in the version most recently provided to Ms. Nowak on July 22, 2009 for physicians at USC and UCLA, whether they have clinical experience in the panoply of peripheral procedures, including renal, iliac, and SFA for which Ms. Nowak, and the company, had no approved devices available and promoted for sale.

125. Medtronic's practices with respect to its biliary stents, as described above, were loudly objected to by Ms. Nowak. Ms. Nowak, following a Medtronic legal training, held early in 2007, e-mailed Smeltzer, then her Sales Manager, on March 4, 2007, concerning the unlawful promotion of medical devices within her group. After hearing at the training that off-label promotion was unlawful, and that sales reps could be held individually responsible for such (the DVD presentation of the training includes PowerPoint documents explaining the absence of a "Nuremberg defense"), Ms. Nowak asked "how we as a company ... could be promoting and pushing representatives to sell biliary stents for peripheral vascular and pushing so much, that the 'off-label' sales target is required for winning a trip." "It seems," she continued, "that by requiring the AAA sales force [*i.e.*, the Endovascular Group] to sell peripheral stents that management is putting a tremendous number of people at risk, mostly themselves....We signed up to sell an FDA approved device for its on-label usage." Smeltzer elected not to respond in e-

mail, and instead spoke with Ms. Nowak in person, reminding her that sale of peripheral devices was part of the job.

D. FDA Warnings and the Dangers of Unapproved Use of Biliary Stents

1. Medtronic ignores the FDA's explicit warnings about off-label design and promotion

126. Medtronic has long been aware of the grave danger to patients resulting from placement of unapproved biliary stents into a person's vascular system. The FDA has noted that manufacturers such as Medtronic repeatedly recall biliary stent products when learning of "adverse events that were the result of off-label vascular use."[9] FDA specifically noted that Medtronic was forced to recall its ASSURANT biliary stent system in 2003 because of the danger surrounding its use "in the vasculature."[10] When Mr. Dodd repeatedly warned the company of these dangers during the design and manufacture stage of stent development, he was ignored and retaliated against. When Ms. Nowak raised these concerns in the context of promotion and sale of these devices, she was also ignored and retaliated against. Mounting evidence, however, has documented the injuries to patients that stem from placement of these off-label stents into highly-sensitive areas of the vascular system. The FDA has repeatedly voiced this concern, and well-circulated medical literature has voiced this concern, but Medtronic's off-label design and promotion continues unabated.

127. The conduct detailed above is all the more brazen in light of the fact that the FDA, in 2007, in an unprecedented (recognized by Medtronic as "extraordinarily unique") widely publicized meeting, gave explicit warning to Medtronic and other biliary stent manufacturers to cease and desist in the promotion of off-label use of their biliary stents. As discussed above, on March 12, 2007, Dr. Schultz, Director of the CDRH, and other FDA

[9] Special Communication, at 968.
[10] *Id.*

personnel, met with executives from various biliary stent manufacturers, including Medtronic. FDA warned the companies, including Medtronic, of its concern about the knowing, willful promotion of biliary stents for unapproved vascular uses. FDA concern was ignored by Medtronic, and the conduct continued.

128. At the meeting, the FDA expressed its great concern about the substantial number of biliary stent malfunctions reported to the FDA "adverse events" database. As the volume of off-label design and promotion of biliary stents has increased in the past ten years, so too have the number of injuries and deaths resulting from this off-label fraud. Dr. Schultz added that the adverse events were almost all reported by doctors using biliary stents for unapproved uses in the arteries, *i.e.*, for vascular uses. Dr. Schultz further noted that the promotion and use of biliary stents for off-label application is a public health issue. On behalf of FDA, he demanded that the respective companies, including Medtronic, submit detailed plans, within three weeks, outlining the efforts the companies would take to better monitor and prevent their sales reps from promoting off-label, and their efforts to inform customers about unapproved use. Medtronic made superficial adjustments to its corporate and sales structure, but did nothing to reign in its off-label design and promotion of biliary stents, including the soon-to-be-fraudulently-submitted COMPLETE SE stent.

129. Although the FDA meeting, attended by Ward, Jayaraman and others, was held in early March 2007, Medtronic waited over five months, until August 31, 2007, to send a letter, from Medtronic's Chief Medical Officer, Coronary and Peripheral (and VP of Medical Affairs - Vascular) LeRoy LeNarz, M.D., advising potential biliary stent customers that the "FDA recently met with all of the manufacturers of biliary stents expressing concern about reports of serious adverse events associated with off-label use of biliary stents in conjunction with vascular

therapy, including *death, seizure, stroke, thrombosis, and vessel perforation.*" (Emphasis added.) The letter concedes that Medtronic's biliary stents "Medtronic Racer, Bridge Assurant, and Aurora" (prior to the approval of COMPLETE SE) are only "cleared by the FDA for palliation of malignant neoplasm in the biliary tree."

130. Indefensibly, sales representatives within the Vascular Division were not informed of the March FDA meeting, or the letter in response, until late September of 2007. At the prompting of Ms. Nowak, who had recently learned of the letter from a physician-client who himself received it from Medtronic, Moeller, in a widely disseminated e-mail dated September 24, 2007, stated "we apologize for the lack of communication to the sales representatives...." Rather than disrupting the off-label promotion and sale of its biliary stents following the FDA meeting, Medtronic elected to remain silent and only belatedly inform its sales force about FDA demands.

131. A follow-up teleconference was held within Medtronic on September 25, 2007, to discuss the March 2007 FDA meeting, and Medtronic's response. This teleconference was recorded and available for sales reps, and others, to inquire of Medtronic executives about the FDA issues. Medtronic executives, including Brennan Marilla (VP of Endovascular U.S. Sales), Dr. LeNarz, Moeller, and others, joined in the call, and explained that the FDA "more or less...summoned" them to the table, and directed them to take action, alerting the companies that both they and Congress "would be watching." A Medtronic employee asked during the call whether it was fair, considering the "layoff of our peripheral sales force and all that," to "justify the coronary sales force taking on that bag." The executives answered that the dissolution of the peripheral group "really didn't have anything to do with what the FDA has requested of us," but

rather, "is more of a strategic decision" designed to align the "vascular teams and the coronary teams" with the doctors who utilize their biliary stents (for off-label use).

132. Smeltzer, in addressing Ms. Nowak's concern regarding Medtronic's continued promotion of biliary devices in light of the recent FDA warning not to do so, instructed her, via e-mail on September 13, 2007, to inform her customers that the "FDA is asking us to remind physicians that these [biliary] stents are approved for biliary use and do not have FDA approval for vascular use… [and that] Medtronic has never completely tested these stents in the vasculature and that we can not guarantee their safety if used in an off label application." In attempting to explain the practice, Smeltzer continued, "you know this has been going on for a long time…[s]o this is a sticky point for all involved, FDA, doctors, and companies. Getting a vascular indication will mean long approval times for new stents…I have always wondered why the FDA let this go on for so long." In fact, Medtronic deceived the FDA for years through its fraudulent use of the 510(k) approval process, creating obstacles to effective enforcement.

133. Medtronic indeed responded to this FDA warning by dissolving and reintegrating the peripheral sales force, attempting to destroy all evidence of its unlawful biliary stent promotional materials, waiting many months to issue a warning letter to customers, and many months to inform its sales reps of FDA involvement. It attempted, in other words, to pacify the FDA without any change in its unlawful behavior. Medtronic has not curbed its willful promotion of biliary stents for off-label use – if anything, it has only intensified those efforts.

134. Despite this intensification of effort to promote the sale of its biliary devices, Medtronic also engages in a dishonest campaign to lecture its sales force about the importance of avoiding *overt* off-label promotion. In an e-mail sent by Moeller to the U.S. Sales Force on January 24, 2008, Moeller reminded them, "As you know, the industry's sales practices of [sic]

biliary stents have been under intense scrutiny by the FDA." Attached to the e-mail was a "Do's and Don'ts" for "Biliary Stent Promotional Considerations." While warning the sales force not to "discuss off-label information" he stated that sales reps should not "target or detail physicians for [off-label] biliary stent use...*unless they also may be reasonably expected to use other devices for their FDA-approved or cleared indications.*" (emphasis added). This "warning" is cleverly improper, and gives assurance to the sales force where no such assurance of lawfulness is warranted. Additionally, none of the peripheral sales incentives or requirements has been abandoned.

135. Notably, Medtronic belatedly initiated a study in support of an Iliac indication for its COMPLETE SE biliary stent. On February 20, 2008, Medtronic announced to its sales force that it had "enrolled 6 patients in the Iliac indication trial for COMPLETE SE. The trial will enroll 60 patients at 10 sites." Unlawfully, however, Medtronic continued promoting its COMPLETE SE biliary stent for off-label vascular use *prior to learning* the results of this study and *prior to any approval* by FDA. Medtronic apparently believes it can simply deflect any FDA concern by reference to an early-stage trial, and continue its unlawful promotion without pause. Gay, with a cc to Brad Baxter, stated to his sales force in a February 26, 2008, e-mail, in addition to separately offering "resources/training you need to help you sell peripherals," "I wanted to make sure everyone had the Complete [SE] brochure and FDA approval letter. Good luck with this product." Good luck, that is, in the unlawful, off-label sale and promotion of Medtronic's new biliary stent – the COMPLETE SE.

2. Medtronic ignores the dangers to patient health resulting from its off-label promotion

136. The continued promotion of biliary stents for off-label use is particularly worrisome in light of FDA concerns over significant reporting of adverse effects. The Class III

approval process, circumvented by Medtronic, is designed to prevent this sort of public health danger. Medtronic, in its belated August 31, 2007, letter to biliary stent customers, admitted that "review of serious adverse events for Medtronic's three biliary stents when used in the vascular system revealed reports of vessel perforation and stent dislodgement issues."

137. An article published in the American Journal of Therapeutics highlights the serious public health risks created by Medtronic's off-label promotion.[11] The doctors who co-authored the research set about to determine the number and type of malfunctions and adverse events associated with the off-label use of biliary stents in the peripheral vasculature. After noting that "as much as 90% of biliary stent use occurs in an 'off-label' fashion," and that "minimal data suppor[ts] their clinical effectiveness and safety" in the peripheral vasculature," the study concluded that for biliary stents, 81% of malfunctions, and 87.9% of adverse events occurred during off-label use in the peripheral vasculature.[12] From 2003-2006, the authors conclude, malfunctions were eight times more likely to occur in the peripheral vasculature than the biliary tract (its only approved application).[13]

138. A variety of adverse events occurred among the patient population studied by the authors, as a result of the use of biliary stents in the vasculature. These events ranged from additional need for surgery to retrieve retained device materials, or to repair a ruptured vessel, to serious vascular injury (vessel perforation, dissection, and thrombosis), stroke, heart attack, and death.[14] Adverse events are widely underreported, so the full extent of the danger posed by these

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[11] Jonathan Bridges, M.D. and William H. Maisel, M.D., MPH, "Malfunctions and Adverse Events Associated with Off-Label Use of Biliary Stents in the Peripheral Vasculature," 15 Amer. J. of Therapeutics 1, 12-18 (2008).
[12] *Id.* at 12-15.
[13] *Id.* at 14.
[14] *Id.* at 14-15.

de facto unregulated device applications is, as the authors' state, unknown, creating, in their words, a "significant public health issue."[15]

139. For no reason other than profit, Medtronic has subjected the public to experimental devices for uses not proven safe or effective and not approved by FDA.

140. In addition to endangering public health, Medtronic's conduct in promoting biliary stents for off-label, vascular uses, has resulted in the submission of countless improper claims for reimbursement from federal and state health care programs. These reimbursements are fraudulently induced both because the 510(k) approvals for these devices were based upon (and contingent upon) false and fraudulent statements and certifications, rendering them ineligible for reimbursement as adulterated and misbranded devices, and because reimbursement of such off-label device use is disallowed. The previously discussed sales reports document with great particularity the scores of customers across the country who have been marketed to and sold biliary stents for off-label, unapproved use. Numerous false claims have been, and continue to be, presented to the government for reimbursement by Medtronic customers. These false claims to the government have been improperly reimbursed as a direct result of Medtronic's unlawful and fraudulent activity.

E. Medtronic Unlawfully Retaliates Against Ms. Nowak for her Investigation and Disclosure of Medtronic's Fraudulent Activity

1. Ms. Nowak begins her successful career at Medtronic

141. Ms. Nowak began her successful career in the medical sales industry in 1998. Others eventually took note of her success as a top-10 salesperson at her various places of employment and contacted her with offers from time to time. In early 2005, while employed at C.R. Bard, Ms. Nowak was contacted by a recruiter retained by Medtronic. The recruiter offered

[15] *Id.* at 17.

Ms. Nowak an opportunity to work as a sales representative for Medtronic, with the opportunity to promote and sell cutting-edge technology medical devices.

142. Looking to continue her success in the industry, on May 23, 2005 (near the beginning of Medtronic's fiscal year 2006), Ms. Nowak joined Medtronic's Endovascular Division as a Sales Representative, responsible primarily for the sale of the AneuRx Graft System (discussed *supra*). Ms. Nowak primarily sold this device to vascular and cardiothoracic surgeons, and some cardiologists and interventional radiologists, to treat Abdominal Aortic Aneurysms. Brad Baxter, who subsequently became a Regional Manager and later Area Director at Medtronic, originally trained Ms. Nowak for approximately two weeks after she joined Medtronic, and her training continued with others thereafter.

143. At that time, Ms. Nowak reported to her immediate supervisor John Smeltzer, then the Pacific Region Manager supervising roughly 13 sales representatives and clinical specialists in the region promoting the same devices. Smeltzer's territory was divided thereafter, and Lowery Gay became Regional Manager responsible for southern California and Arizona, including Mr. Nowak's territory. Mr. Gay reported to Baxter, who reported to Brennan Marilla.

144. When she began at Medtronic in May of 2005, Ms. Nowak's sales territory stretched roughly from Highway-10 in southern Los Angeles, north to Fresno, California, east to San Antonio Community Hospital in Upland, California and west to the California coast. Ms. Nowak was not in charge of all the accounts within those boundaries, but her sales territory was roughly within those parameters. When she began work with Medtronic, she was told by Smeltzer that her territory was the "Wild West" because Medtronic had such little business in the area. Ms. Nowak grew significant business in that territory in the years that followed, earning her praise from Medtronic executives.

145. Initially, Ms. Nowak was placed on a 6-month "guarantee" or "training" period where she was not expected to grow the business but instead to learn the products and the relevant therapies, while others continued to sell devices in her territory. Eventually, as described further below, she set about to, and ultimately succeeded in, growing the business and revenue within her territory by increasing the sale and use of Medtronic's products.

146. Ms. Nowak exceeded her sales quota for the balance of fiscal year 2006, and in her first full fiscal year of sales, 2007 (which stretched from May of 2006 through April of 2007), she exceeded her annual revenue target (termed an "AOP" by Medtronic) at roughly 112% of quota year-to-date, and nearly 100% year-to-year territory revenue growth. On February 2, 2007 she received a letter from Katie Syzman, then Vice President and General Manager of Endovascular Innovations, "personally thank[ing]" Ms. Nowak for her efforts in surpassing her AOP in the preceding fiscal quarter "with an overall Q3 sales ranking of #6 in the country" with "81% year to date" growth in her AneuRx business. Syzman ended the letter "[y]our hard work does not go unnoticed and is very much appreciated. Keep up the tremendous job!"

2. Ms. Nowak continues to grow Medtronic's business and informs Medtronic of her objections to the off-label promotion of biliary stents

147. As discussed above, fearing increased government scrutiny over the unlawful, off-label promotion of biliary stents, rather than discontinuing the practice until approval of vascular uses by the FDA for these devices, Medtronic simply transferred responsibilities to other divisions where the practice was more easily disguised. At a company meeting in Las Vegas, attended by Ms. Nowak, both Marilla and Syzman informed sales representatives in the Endovascular Divisions that Medtronic would begin requiring peripheral stent sales from those two sales groups. That is, off-label biliary stent sales. Ms. Nowak and others were told it would

be "pretty easy" to sell such devices because of the good relationships already established from the on-label selling of other devices to Medtronic customers. In other words, the sales force was instructed to leverage the trust they had built with physicians from on-label sales to generate off-label business with biliary stents.

148. Ms. Nowak was immediately uncomfortable with the idea of promoting and selling these devices for an off-label use – she and her colleagues having never been trained or otherwise educated on the approved uses of biliary stents. To Ms. Nowak's knowledge no division, group, or unit of Medtronic was ever trained or tasked with selling biliary stents for their limited, approved, on-label use – certainly no one was tasked with selling to the doctors who perform on-label biliary stent surgeries.

149. Ostensibly encouraged by company policy at Medtronic to report any concerns over unethical practices at the company, on March 4, 2007, following a mandatory ethics training program that addressed off-label issues and FDA law, Ms. Nowak sent an email to Smeltzer (quoted *supra* in part) expressing serious concern about the requirement that the sales force promote and sell peripheral products, specifically biliary stents, off-label.

> John,
>
> After reviewing, taking notes, and thinking about our required BCS training, I have several questions for you and Medtronic's management team relating to selling peripheral stents. From the video that we were required to watch, Terry Carlson stated that we at Medtronic have specific guidelines for off-label uses and selling of devices. I would like to know where I can obtain a copy of them. He also stated that the "Nuremberg" defense of behavior was no longer acceptable. So, I do not understand how we as a company, knowing that we are a target for government investigations, could be promoting and pushing representatives to sell biliary stents for peripheral vascular and pushing so much, that the "off-label" sales target is required for winning a trip.
>
> It is not reasonable to say that because other companies are selling peripheral it is legitimate for us to do so. Nor is it reasonable to

> say that Pioneer was an option for the peripheral target because it has not been available. I can't believe that I am the only person who would question the integrity and the ethics of this "strategy." From the training which we were required to do, it seems that this would not be unethical, but illegal according to the FDA standards. Especially considering that we received a voicemail a couple of months ago that the FDA was not approving new peripheral devices because of their concern over off-label usage. I really do understand the mindset that "everyone" is doing it and profiting from it. But, the same thing could be said [*sic*] Enron, Arthur Anderson, concentration camps, etc…
>
> In the video, it also stated that Medtronic's new management model is Proactive and not reactive. The notes that I took from the video were that "management must ensure that there is ethics/compliance programs to prevent, detect, and respond to violations…" It seems that by requiring the AAA sales force to sell peripheral stents that management is putting a tremendous number of people at risk, mostly themselves. (Also, the hypocrisy of the request to sell off-label devices then requiring legal training is baffling.) I realize that there are entire divisions of companies that are doing well by selling the biliary stents for off-label vascular procedures, but the people at this division did not sign up for those jobs. If we, specifically, I, were comfortable doing that I would have taken a job with Gore, Boston Sci, or any of the other companies doing this. However, I & we, did not. We signed up to sell an FDA approved device for its on-label usage.
>
> Please provide written feedback on this.
>
> Thank you, Tricia Nowak Sales Representative Medtronic

150. No written response to Ms. Nowak's email was ever provided. On March 19, 2007, Ms. Nowak forwarded the above email, as well as a March 15 Wall Street Journal article discussing off-label sale of biliary stents and the government's increased attention to the practice, to Marilla. Shortly thereafter, Marilla directed Ms. Nowak to be in a teleconference with an independent legal consultant, in-house counsel and Marilla wherein her concerns were discussed at length but no action was taken. Medtronic continued its unlawful off-label activities and requirements for off-label peripheral sales without hesitation.

151. Ms. Nowak also discussed her ethical and legal concerns with colleagues, and discussed with them whether they ought to report the company practices to FDA. They expressed to her fear of retaliation, and declined any further involvement.

152. As discussed at length above, within days of Ms. Nowak's email transmission, on March 12, 2007, the FDA summoned executives from the various biliary stent manufacturers, including Medtronic, and warned the companies about the unlawfulness of knowing, willful promotion of biliary stents for off-label vascular use. Soon thereafter, Medtronic dissolved its Peripheral Group, and (as noted above) created the CardioVascular Division. With full knowledge that the Government was watching its practices - the Wall Street Journal, Endovascular Today, and other media having detailed the issues - and having received an express complaint regarding such activity from Ms. Nowak, Medtronic elected to continue its unlawful off-label promotion and sale of biliary stents. Ms. Nowak continued to express her objections to Smeltzer and other superiors at Medtronic in 2007 – but to no avail.

153. Ms. Nowak continued her extraordinary sales performance into Medtronic's fiscal year 2008 (*i.e.*, the balance of calendar year 2007, and into 2008). In November of 2007 she received written praise from Marilla, then VP of U.S. Sales for Medtronic Vascular, for her "fantastic" fiscal quarter, her "outstanding performance and strong finish" and her "hard work, winning attitude and professionalism."

154. Ms. Syzman also wrote on December 3, 2007, to "personally thank" her for "efforts in surpassing your AOP in Q2, FY2008" during which her "AneuRx percent to plan was 121.8% and your Reliant percent to plan was 130.7%, with an overall Q2 sales ranking of #11 in the country." Syzman wrote again on February 8, 2008, thanking Ms. Nowak for "extraordinary efforts" to achieve a "Q3 sales ranking of #13 in the country."

155. On February 15, 2008 Gay wrote to Ms. Nowak in praise of her "tremendous success this year," managing to be "one of only two people in our region who was able to...exceed[] AOP all three quarters." "This is a testament to your work ethic," Gay noted.

156. Also in early 2008, as discussed above, Medtronic added the COMPLETE SE to its line of biliary stents, promoted off-label for vascular use. Ms. Nowak's sales group was immediately pressured to sell the COMPLETE SE despite the fact that clinical trials were not yet completed on the product. Again, the FDA had given it only a limited approval, as with Medtronic's other biliary devices, for use in the bile duct, *not* in the vascular system. Gay repeatedly told Ms. Nowak, both orally and in emails and written evaluations, that she needed to promote biliary stents as a job requirement. She repeated each time that she believed such promotion to be illegal, and that she would not violate the law by promoting them.

157. On March 5, 2008, Ms. Nowak filed her original *qui tam* complaint against Medtronic, under seal, in the District of Massachusetts. She subsequently filed an amended complaint on April 17, 2008. By that time Ms. Nowak's colleagues would often joke with her, and tease her about her "high-minded" principles in refusing to promote biliary stents even though it was lucrative to do so. They also joked that many people believed she would report Medtronic to the FDA or file a lawsuit to address Medtronic's unlawful activity.

158. Despite this pressure, Ms. Nowak continued to excel in her performance through the end of fiscal year 2008. Near the start of fiscal year 2009, on June 5, 2008, Syzman again sent Ms. Nowak a letter praising her performance, noting her "outstanding efforts in surpassing [her] AOP in Q408." The letter concluded – "Your hard work makes a difference in many patients' lives and it is very much appreciated. It has been great working with you and I wish you a fantastic FY09!" Her performance evaluation for FY08 noted, "[y]ou had a tremendous

sales year in FY08. During a year that saw Medtronic Endo challenged with a Field Action, a PHI, and inventory struggles, you came through. Your performance was above plan and consistent. The results speak for themselves, Q1 112% to AOP, Q2 122 to AOP, Q3 111% to AOP, and in Q4 104% to AOP!"

159. Within weeks of Ms. Nowak being recognized by executives as a top performer, on July 2, 2008, Medtronic, through Janice Symchych (VP and Deputy General Counsel) distributed a "preservation of documents" legal notice in a company-wide transmission to its employees, noting that it had received a subpoena from the United States Attorneys Office in the District of Massachusetts, "which requests production of a wide variety of documents relating to biliary stents." Medtronic itself made this DOJ request publicly known. Ms. Nowak also reviewed a "Voice Your Concern" document from Medtronic that explained, among other things, the various provisions of the False Claims Act and its applicability to Medtronic.

160. During the months to follow, Medtronic developed a plan and a pretext to terminate Ms. Nowak as a result of her protected activity.

161. Ms. Nowak, nonetheless, continued to excel. At the end of October 2008, the close of Q2 for fiscal year 2009, Ms. Nowak was 129% to Plan (the second highest in her region).

3. Medtronic retaliates against and ultimately terminates Ms. Nowak for her protected activity under the False Claims Act

162. In 2009, despite the fact that numerous other sales representatives underperformed in the past, and in the present, Ms. Nowak was singled out and targeted for her whistleblowing activity, under the pretext that her performance numbers were not acceptable.

163. Though many other sales representatives missed their sales targets then and in the past, had declining growth, and drops in sales quotas, and despite her being one of Medtronic's

top sales representatives during her tenure, on February 6, 2009 Baxter and Gay required Ms. Nowak to attend a meeting with them, where they explained that she would be placed on probation with a Performance Improvement Plan ("Plan I") requiring her to uniquely satisfy a host of performance targets or risk termination. Ms. Nowak inquired why, given her stellar performance record at Medtronic, the general performance at the time, and the performance of many other sales representatives, she was being singled out with these performance requirements. Baxter responded that it was "irrelevant" to ask about the treatment of other sales representatives or the company generally.

164. This discriminatory and retaliatory action was designed to create a pretext for retaliatory discharge – the risk of allowing a whistleblower to continue with the company being greater than the risk and cost of a retaliation lawsuit. Medtronic was aware that satisfaction of these unique and newly adopted performance standards for Ms. Nowak alone was unreasonable – which was their intent. On March 11, 2009, with a month and a half left in Q4 2009 fiscal year, Plan I was sent to Ms. Nowak for signature.

165. Shortly thereafter, Ms. Nowak met with Baxter and, on March 13, told him she did not believe she deserved to be on a Plan. Baxter said not to worry, that the company would not seek to terminate a "top performer" who "never missed an annual number since being at Medtronic."

166. At the start of fiscal year 2010, Medtronic continued the pretext of "performance-based" sanctions by placing Ms. Nowak on a subsequent Performance Improvement Plan ("Plan II") on May 8, 2009. In anticipation of terminating Ms. Nowak, Plan II required her to split her most lucrative, and largest customers (so-called Tier 1 accounts – USC, UCLA, and Cedars Sinai) with another sales representative. Under the pretext of putting more effort into "growing"

the business, Medtronic was able to both transition Ms. Nowak's customers away from her prior to her termination and cut into her revenue potential (and compensation) by requiring that her revenue amounts be split with Danny Lewis (who continued to sell off-label and receive ongoing praise for it). This retaliatory action further insured she would fail to satisfy the revenue performance standards imposed upon her, and her alone.

167. Both preceding and during the time period of both Plan I and Plan II, Ms. Nowak was denied the resources necessary for training and support for her physician-customers, which directly effected her ability to meet revenue goals.

168. Ms. Nowak also became aware during the summer that Medtronic was actively recruiting for her position prior to notifying her they intended to fire her. Such an effort was demoralizing for Ms. Nowak who was expected to grow business while customers inquired whether she was going to continue working with the products she was selling.

169. On August 4, 2009, reporting on the territory's overall performance in the first quarter of fiscal year 2010 (May, June and July of calendar year 2009) Gay informed his sales team via email, including Ms. Nowak, that overall revenue had fallen in the region, that most sales representatives had failed to meet their respective plan numbers, and that the region struggled. Despite this, Ms. Nowak was isolated, targeted, discriminated and retaliated against, and finally terminated under a pretext of non-performance.

170. Finally, on August 7, 2009, Gay and Ron Morgan, from Human Resources, met with Ms. Nowak and fired her from Medtronic. During their meeting at the Renaissance Hotel in Hollywood, Ms. Nowak was offered a voluntary separation package to sign. She was told to take some time to think about it before accepting or declining. Ms. Nowak declined to sign any severance agreement or voluntary termination documents, and was instead involuntarily

terminated. Morgan attempted to assure Ms. Nowak that signing the documents simply precluded her from involvement in any class action lawsuit, but would allow her to individually pursue suit against Medtronic. Gay also recommended that they agree upon "consistent messaging" regarding Ms. Nowak's "separation" from the company. Mr. Morgan claimed to have met with Marilla, Baxter and the legal department about the decision to "part ways" with Ms. Nowak. Gay offered to Ms. Nowak the pretext for her termination - a "lack of intensity."

171. Ms. Nowak followed this meeting by notifying Morgan via email that she was not agreeing to a separation or termination from the company, and would not be signing any documents to that effect. The termination was entirely and utterly involuntary – and retaliatory.

COUNT I

FEDERAL FALSE CLAIMS ACT

31 U.S.C. §§ 3729(a)(1)(A) and (a)(1)(B)

172. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 171 of this Complaint.

173. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, as amended.

174. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval, and made, used and caused to be made and used false records and statements material to false claims. Each claim for reimbursement for use of Medtronic's biliary stents represents a false or fraudulent claim for payment given that these devices' approvals were obtained by false certifications and statements to the FDA and are thereby unapproved, were promoted off-label, and each claim based upon off-label use of biliary stents constitutes a false or fraudulent claim

for payment because such off-label uses are not approved for reimbursement by the federal Government.

175. Plaintiffs cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

176. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by the Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion of off-label use.

177. By reason of the Defendant's acts, the United States has been damaged, and continues to be damaged, in substantial amounts to be determined at trial. Federal health care programs have paid significant amounts for the unapproved biliary stents that continue to be unapproved for vascular uses by the FDA.

COUNT II

CALIFORNIA FALSE CLAIMS ACT

Cal. Gov't Code § 12651(a)(1) and (2)

178. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 171 of this Complaint.

179. This is a claim for treble damages and penalties under the California False Claims Act.

180. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval. Each claim for reimbursement of unapproved biliary devices illegally promoted off-

label and submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

181. Plaintiffs cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

182. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

183. By reason of the Defendant's acts, the State of California has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

184. The State of California is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT III

DELAWARE FALSE CLAIMS AND REPORTING ACT

6 Del. Code Ann. § 1431(a)(1) and (2)

185. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 171 of this Complaint.

186. This is a claim for treble damages and penalties under the Delaware False Claims And Reporting Act.

187. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or

approval. Each claim for reimbursement of unapproved biliary devices illegally promoted off-label and submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

188. Plaintiffs cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

189. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

190. By reason of the Defendant's acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

191. The State of Delaware is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT IV

FLORIDA FALSE CLAIMS ACT

Fla. Stat. Ann. § 68.082(2)(a) and (b)

192. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 171 of this Complaint.

193. This is a claim for treble damages and penalties under the Florida False Claims Act.

194. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or

approval. Each claim for reimbursement of unapproved biliary devices illegally promoted off-label and submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

195. Plaintiffs cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

196. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

197. By reason of the Defendant's acts, the State of Florida has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

198. The State of Florida is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT V

GEORGIA STATE FALSE MEDICAID CLAIMS ACT

O.C.G.A. § 49-4-168.1(a)(1) and (2)

199. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 171 of this Complaint.

200. This is a claim for treble damages and penalties under the Georgia State False Medicaid Claims Act.

201. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or

approval. Each claim for reimbursement of unapproved biliary devices illegally promoted off-label and submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

202. Plaintiffs cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

203. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

204. By reason of the Defendant's acts, the State of Georgia has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

205. The State of Georgia is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT VI

HAWAII FALSE CLAIMS ACT

Haw. Rev. Stat. § 661-21(a)(1) and (2)

206. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 171 of this Complaint.

207. This is a claim for treble damages and penalties under the Hawaii False Claims Act.

208. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or

approval. Each claim for reimbursement of unapproved biliary devices illegally promoted off-label and submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

209. Plaintiffs cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

210. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

211. By reason of the Defendant's acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

212. The State of Hawaii is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT VII

ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

740 Ill. Comp. Stat. § 175/3(a)(1) and (2)

213. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 171 of this Complaint.

214. This is a claim for treble damages and penalties under the Illinois Whistleblower Reward And Protection Act.

215. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or

approval. Each claim for reimbursement of unapproved biliary devices illegally promoted off-label and submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

216. Plaintiffs cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

217. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

218. By reason of the Defendant's acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

219. The State of Illinois is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT VIII

INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

Ind. Code Ann. § 5-11-5.5-2(b)(1) and (8)

220. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 171 of this Complaint.

221. This is a claim for treble damages and penalties under the Indiana False Claims and Whistleblower Protection Act.

222. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or

approval. Each claim for reimbursement of unapproved biliary devices illegally promoted off-label and submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

223. Plaintiffs cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

224. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful conduct.

225. By reason of the Defendant's acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

226. The State of Indiana is entitled a penalty of at least $5,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT IX

LOUISIANA MEDICAL ASSISTANCE PROGRAM INTEGRITY LAW

La. Rev. Stat. § 46:437.1, *et seq.*

227. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 171 of this Complaint.

228. This is a claim for treble damages and penalties under the Louisiana Medical Assistance Program Integrity Law.

229. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or

approval. Each claim for reimbursement of unapproved biliary devices illegally promoted off-label and submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

230. Plaintiffs cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

231. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

232. By reason of the Defendant's acts, the State of Louisiana has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

233. The State of Louisiana is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT X

MASSACHUSETTS FALSE CLAIMS LAW

Mass. Gen. Laws Ch. 12 § 5B(1) and (2)

234. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 171 of this Complaint.

235. This is a claim for treble damages and penalties under the Massachusetts False Claims Law.

236. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts State Government for payment or

approval. Each claim for reimbursement of unapproved biliary devices illegally promoted off-label and submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

237. Plaintiffs cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

238. The Massachusetts State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

239. By reason of the Defendant's acts, the State of Massachusetts has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

240. The State of Massachusetts is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT XI

MICHIGAN MEDICAID FALSE CLAIMS ACT

Mich. Comp. Laws § 400.601, et seq.

241. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 171 of this Complaint.

242. This is a claim for treble damages and penalties under the Michigan Medicaid False Claims Act.

243. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Michigan State Government for payment or approval. Each claim for reimbursement of unapproved biliary devices illegally promoted off-label and submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

244. Plaintiffs cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

245. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

246. By reason of the Defendant's acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

247. The State of Michigan is entitled to the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT XII

MONTANA FALSE CLAIMS ACT

Mont. Code Ann. § 17-8-403(1)(a) and (b)

248. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 171 of this Complaint.

249. This is a claim for treble damages and penalties under the Montana False Claims Act.

250. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Montana State Government for payment or approval. Each claim for reimbursement of unapproved biliary devices illegally promoted off-label and submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

251. Plaintiffs cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

252. The Montana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

253. By reason of the Defendant's acts, the State of Montana has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

254. The State of Montana is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT XIII

NEVADA FALSE CLAIMS ACT

Nev. Rev. Stat. Ann. § 357.040(1)(a) and (b)

255. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 171 of this Complaint.

256. This is a claim for treble damages and penalties under the Nevada False Claims Act.

257. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval. Each claim for reimbursement of unapproved biliary devices illegally promoted off-label and submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

258. Plaintiffs cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

259. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

260. By reason of the Defendant's acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

261. The State of Nevada is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT XIV

NEW HAMPSHIRE FALSE CLAIMS ACT

N.H. Rev. Stat. Ann. § 167:61(1)(a) and (b)

262. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 171 of this Complaint.

263. This is a claim for treble damages and penalties under the New Hampshire False Claims Act.

264. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the New Hampshire State Government for payment or approval. Each claim for reimbursement of unapproved biliary devices illegally promoted off-label and submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

265. Plaintiffs cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

266. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

267. By reason of the Defendant's acts, the State of New Hampshire has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

268. The State of New Hampshire is entitled to the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT XV

NEW JERSEY FALSE CLAIMS ACT

N.J. Stat. Ann. § 2a:32C-3(a) and (b)

269. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 171 of this Complaint.

270. This is a claim for treble damages and penalties under the New Jersey False Claims Act.

271. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the New Jersey State Government for payment or approval. Each claim for reimbursement of unapproved biliary devices illegally promoted off-label and submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

272. Plaintiffs cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

273. The New Jersey State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

274. By reason of the Defendant's acts, the State of New Jersey has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

275. The State of New Jersey is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT XVI

NEW MEXICO MEDICAID FALSE CLAIMS ACT

N.M. Stat. Ann. § 27-14-4(A)-(C)

276. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 171 of this Complaint.

277. This is a claim for treble damages and penalties under the New Mexico Medicaid False Claims Act.

278. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval. Each claim for reimbursement of unapproved biliary devices illegally promoted off-label and submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

279. Plaintiffs cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

280. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

281. By reason of the Defendant's acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

282. The State of New Mexico is entitled to the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT XVII

NEW YORK FALSE CLAIMS ACT

N.Y. Cls St. Fin. § 189(1)(a) and (b)

283. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 171 of this Complaint.

284. This is a claim for treble damages and penalties under the New York Medicaid False Claims Act.

285. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the New York State Government for payment or approval. Each claim for reimbursement of unapproved biliary devices illegally promoted off-label and submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

286. Plaintiffs cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

287. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

288. By reason of the Defendant's acts, the State of New York has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

289. The State of New York is entitled to the maximum penalty of $12,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT XVIII

OKLAHOMA MEDICAID FALSE CLAIMS ACT

Okla. Stat. 63 § 5053.1(b)(1) and (2)

290. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 171 of this Complaint.

291. This is a claim for treble damages and penalties under the Oklahoma Medicaid False Claims Act.

292. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Oklahoma State Government for payment or approval. Each claim for reimbursement of unapproved biliary devices illegally promoted off-label and submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

293. Plaintiffs cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

294. The Oklahoma State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by

Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

295. By reason of the Defendant's acts, the State of Oklahoma has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

296. The State of Oklahoma is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT XIX

RHODE ISLAND STATE FALSE CLAIMS ACT

R.I. Gen. Laws § 9-1.1-3(a)(1) and (2)

297. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 171 of this Complaint.

298. This is a claim for treble damages and penalties under the Rhode Island State False Claims Act.

299. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Rhode Island State Government for payment or approval. Each claim for reimbursement of unapproved biliary devices illegally promoted off-label and submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

300. Plaintiffs cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

301. The Rhode Island State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

302. By reason of the Defendant's acts, the State of Rhode Island has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

303. The State of Rhode Island is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT XX

TENNESSEE MEDICAID FALSE CLAIMS ACT

Tenn. Code Ann. §§ 71-5-182(a)(1)(A) and (B)

304. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 171 of this Complaint.

305. This is a claim for treble damages and penalties under the Tennessee Medicaid False Claims Act.

306. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval. Each claim for reimbursement of unapproved biliary devices illegally promoted off-label and submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

307. Plaintiffs cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate

entities, across the United States, over many years. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

308. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

309. By reason of the Defendant's acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

310. The State of Tennessee is entitled to the maximum penalty of $25,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT XXI

TEXAS MEDICAID FRAUD PREVENTION LAW

Tex. Hum. Res. Code Ann. § 36.002(1) and (4)

311. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 171 of this Complaint.

312. This is a claim for treble damages and penalties under the Texas Medicaid Fraud Prevention Law.

313. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval. Each claim for reimbursement of unapproved biliary devices illegally promoted off-label and submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

314. Plaintiffs cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

315. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

316. By reason of the Defendant's acts, the State of Texas has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

317. The State of Texas is entitled to the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT XXII

VIRGINIA FRAUD AGAINST TAXPAYERS ACT

VA. Code Ann. § 8.01-216.3(a)(1) and (2)

318. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 171 of this Complaint.

319. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

320. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Virginia State Government for payment or approval. Each claim for reimbursement of unapproved biliary devices illegally promoted off-label and submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

321. Plaintiffs cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

322. The Virginia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

323. By reason of the Defendant's acts, the State of Virginia has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

324. The State of Virginia is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT XXIII

WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE ACT

Wis. Stat. § 20.931(2)(a) and (b)

325. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 171 of this Complaint.

326. This is a claim for treble damages and penalties under the Wisconsin False Claims for Medical Assistance Act.

327. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Wisconsin State Government for payment or approval. Each claim for reimbursement of unapproved biliary devices illegally promoted off-label and submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

328. Plaintiffs cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

329. The Wisconsin State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

330. By reason of the Defendant's acts, the State of Wisconsin has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

331. The State of Wisconsin is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT XXIV

DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT

D.C. Code Ann. § 2-308.14(a)(1) and (2)

332. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 171 of this Complaint.

333. This is a claim for treble damages and penalties under the District of Columbia Procurement Reform Amendment Act.

334. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval. Each claim for reimbursement of unapproved biliary devices illegally promoted off-

label and submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

335. Plaintiffs cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

336. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

337. By reason of the Defendant's acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

338. The District of Columbia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT XXV

FALSE CLAIMS ACT

31 U.S.C. § 3730(H)

339. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1-171 of this Second Amended Complaint.

340. By terminating the employment of Ms. Nowak, and otherwise discriminating and retaliating against her, Medtronic violated 31 U.S.C. § 3730(h), which prohibits an employer from discharging or otherwise discriminating against or retaliating against an employee because

of acts undertaken by that employee in furtherance of stopping violations of the False Claims Act.

341. As a result of Medtronic's wrongful actions, Ms. Nowak suffered and continues to suffer substantial damage.

COUNT XXVI

CALIFORNIA FALSE CLAIMS ACT

CAL. GOV'T. CODE § 12653(B)

342. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1-171 of this Second Amended Complaint.

343. By terminating the employment of Ms. Nowak, and otherwise retaliating against her, Medtronic violated California Government Code § 12653(b), which prohibits an employer from discharging, or in any manner discriminating against or retaliating against an employee because of acts undertaken by that employee in disclosing to the government or otherwise furthering a false claims action.

344. As a result of Medtronic's wrongful actions, Ms. Nowak suffered and continues to suffer substantial damage.

COUNT XXVII

WRONGFUL DISCHARGE IN VIOLATION OF PUBLIC POLICY UNDER CALIFORNIA COMMON LAW

345. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1-171 of this Second Amended Complaint.

346. By wrongfully terminating Ms. Nowak, defendant Medtronic caused injury to her in contravention of fundamental public policy, embodied in the California False Claims Act at Cal. Gov't Code § 12650-12655, the Cal. Labor Code § 1102.5, and the State's penal and civil

anti-fraud statutes, which prohibit an employer from discharging, or in any manner discriminating against or retaliating against an employee because of acts undertaken by that employee in disclosing information to the government or otherwise furthering the reporting or investigation of fraud and other wrongdoing.

PRAYER

WHEREFORE, Plaintiffs pray for judgment against the Defendant as follows:

A. That Defendant cease and desist from violating 31 U.S.C. § 3729, *et seq.* and the equivalent provisions of the State statutes set forth above;

B. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the United States has sustained because of Defendant's actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. § 3729;

C. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of California has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of CAL. GOV'T CODE § 12651(a);

D. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Delaware has sustained because of Defendant's actions, plus a civil penalty of $11,000 for each violation of 6 DEL. CODE ANN. § 1431(a);

E. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Florida has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of FLA. STAT. ANN. § 68.082(2);

F. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Georgia has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of O.C.G.A. § 49-4-168.1(a).

G. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Hawaii has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of HAW. REV. STAT. § 661-21(a);

H. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Illinois has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of 740 ILL. COMP. STAT. § 175/3(a);

I. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Indiana has sustained because of Defendant's actions, plus a civil penalty of at least $5,000 for each violation of IND. CODE ANN. § 5-11-5.5-1.2(b);

J. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Louisiana has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of LA. REV. STAT. § 46:437.1, *et seq.*;

K. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Massachusetts has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of MASS. GEN. L. CH. 12 § 5B;

L. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Michigan has sustained because of Defendant's actions, plus civil penalties for each violation of MICH. COMP. LAWS. § 400.601, *et seq.*;

M. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Montana has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of MONT. CODE ANN. § 17-8-403(1);

N. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Nevada has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of NEV. REV. STAT. ANN. § 357.040(1);

O. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of New Hampshire has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of N.H. REV. STAT. ANN. § 167:61-1;

P. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of New Jersey has sustained because of Defendant's actions, plus civil penalties of $11,000 for each violation of N.J. STAT. ANN. § 2A:32C-3;

Q. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of New Mexico has sustained because of Defendant's actions, plus civil penalties for each violation of N.M. STAT. ANN. § 27-14-4;

R. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of New York has sustained because of Defendant's actions, plus a civil penalty of $12,000 for each violation of N.Y. CLS ST. FIN. § 189(1);

S. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Oklahoma has sustained because of Defendant's actions, plus a civil penalty of $10,000 each violation of OKLA. STAT. 63 § 5053.1(b);

T. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Rhode Island has sustained because of Defendant's actions, plus a civil penalty for each violation of R.I. GEN. LAWS. § 9-1.1-3(a);

U. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Tennessee has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of TENN. CODE ANN. § 71-5-182(a)(1);

V. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Texas has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of TEX. HUM. RES. CODE ANN. § 36.002;

W. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Virginia has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of VA. CODE ANN. § 8.01-216.3(a);

X. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Wisconsin has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of WIS. Stat. § 20.931(2);

Y. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the District of Columbia has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of D.C. CODE ANN. § 1-1188.14(a);

Z. That Plaintiffs be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act and the equivalent provisions of the State statutes set forth above;

aa. That Plaintiffs be awarded all costs of this action, including attorneys' fees, costs, and expenses pursuant to 31 U.S.C. § 3730(d) and the equivalent provisions of the State statutes set forth above;

bb. That Plaintiff Ms. Nowak be awarded reinstatement with the same seniority status as she would have but for the discrimination, two times the amount of backpay, interest on the

backpay, and compensation for special damages sustained as a result of the discrimination, as well as litigation costs and attorneys' fees, pursuant to 31 U.S.C. § 3730(h);

cc. That Plaintiff Ms. Nowak be awarded reinstatement with the same seniority status that she would have had but for the discrimination, two times the amount of backpay, interest on the backpay, compensation for special damages sustained as a result of the discrimination, punitive damages, as well as litigation costs and attorneys' fees, pursuant to Cal Gov't Code 12653(c);

dd. That Plaintiff Ms. Nowak be awarded all available damages and injunctive relief resulting from her wrongful termination, as well as litigation costs and attorneys' fees, pursuant to California common law; and

ee. That the United States, the States, and Plaintiffs/Relators be granted all such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs hereby demand a trial by jury.

Dated: February 19, 2010

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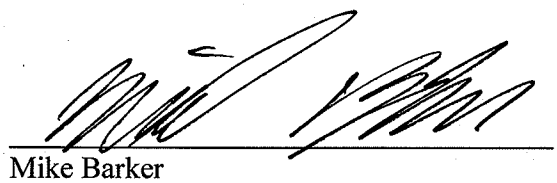
CETRIFICATE OF SERVICE

I hereby certify that on February 19, 2010, I caused the foregoing to be sent, via hand delivery, to the Clerk of the Court for the United States District Court for the District of Massachusetts.

Mike Barker

CETRIFICATE OF SERVICE

I hereby certify that on February 19, 2010, I caused the foregoing to be sent, via hand delivery, to the Clerk of the Court for the United States District Court for the District of Massachusetts.



Mike Barker